Canadian Centre for
Occupational Health
and Safety

Centre canadien
d'hygiène et de
sécurité au travail

Workplace Hazardous Materials Information System Classification

A Workshop

P88-19E

Canadian Centre
for Occupational Health
and Safety

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A Workshop

Hamilton, Ontario

May 17, 1988

Canadian Centre
for Occupational
Health and Safety

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WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEM CLASSIFICATION

A WORKSHOP

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The Canadian Centre
for Occupational Health and Safety

A Workshop

WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEM (WHMIS) CLASSIFICATION WORKSHOP

Tuesday, May 17, 1988
Hamilton Convention Centre, Webster B & C
Hamilton, Ontario

AGENDA

8:15 am	Registration and Coffee
9:00 am	Introduction
	CRITERIA REVIEW Geoff Granville, Manager, Toxicology & Material Safety Shell Canada Limited Chairman: Robert Whiting
	APPLICATION OF CRITERIA FOR SKIN & EYE IRRITATION Richard Morris, Toxicologist, Industrial Chemicals & Product Safety Health and Welfare Canada Chairman: Geoff Granville
	CLASSIFICATION OF MATERIAL 1 Robert Whiting, Manager, Material Hazards Canadian Centre for Occupational Health & Safety Chairman: Peter Robson
12:30 pm	Lunch – Webster A & Lounge
1:30 pm	ARTICLES – DEFINITIONS, POLICIES Open Discussion Chairman: Marc Baril
	CLASSIFICATION OF MATERIAL 2 Marc Baril, Chef de service du répertoire toxicologique Direction du soutien scientifique et théorique CSST (Commission de la santé et de la sécurité du travail du Québec) Chairman: David Gaylor
	CLASSIFICATION OF IMPORTS FROM USA AND EEC David Gaylor, Manager, Occupational Hygiene C-I-L Inc Chairman: Richard Morris
4:30 pm	Close of Workshop

Introduction

Lillian Vine

Ladies and gentlemen, welcome. The interest and enthusiasm to comply with WHMIS are evident by the sell-out crowd at both our first classification workshop in February and now. Bienvenue.

The Centre was officially asked to do a classification workshop at 11:30 p.m. on December 3. There had been some exploratory discussion, but it was possible that after the Canadian Chemical Producers' Association/Canadian Manufacturers' Association seminars one wouldn't be necessary. Just before the end of those seminars last November, Peter Robson, Senior Research Scientist at Du Pont Canada Research Centre, called. He, Geoff Granville and I talked and it looked as if we should go ahead. We put plans together for a very successful workshop very quickly. The February 22 session was sold out virtually as soon as we let people know it would take place. We decided to go ahead with a second one today. It also drew an enthusiastic response.

Our first speaker is Geoff Granville, one of the originators of this workshop. Geoff graduated with a joint degree in Biochemistry and Toxicology in 1972 from the University of Surrey. This was the first course of its type in the world, that is toxicology as a specific degree program, and he was in the first class to graduate.

From 1972-74, he worked as a "practical" toxicologist (getting bitten by rats and mice) in Shell's Toxicology Lab in the UK. He was transferred to Shell International Petroleum Company's Toxicology Division in 1974, where he performed "deskbound" toxicology until 1981. This consisted of recommending studies, reviewing data and providing risk assessments for Shell's oil and chemical business.

In 1981, Shell Canada called, and for the next while he was the Corporate Toxicologist, based in Toronto. In 1984, he was transferred to Calgary as the Manager of Toxicology and Material Safety for Shell Canada Ltd. This job carries the responsibilities for the company's Product Safety and MSDS programs, as well as for toxicological matters.

Geoff will begin with a criteria review and set the tone for the workshop. The chairman for this session is Bob Whiting of the Centre.

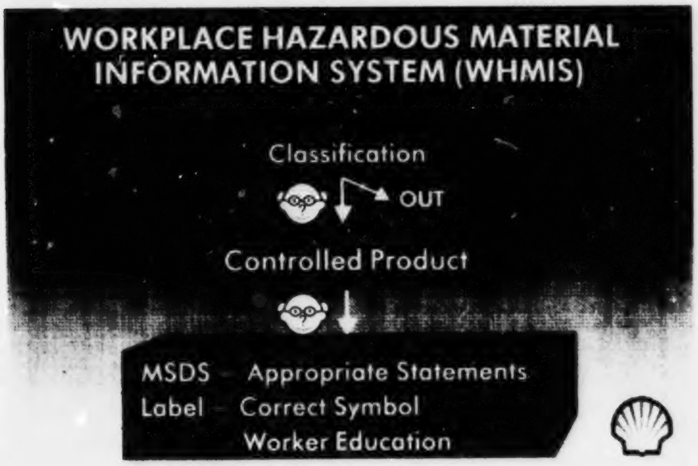
Criteria Review

Presenter: Geoff Granville
Chairman: Robert Whiting

The classification problem has yet to be fully aired; at the end of last year a number of us were thinking how important it would be to have a good workshop to talk about it. Consistency in classification is going to be a major problem in showing that WHMIS is effectively initiated and that the WHMIS regulations are properly complied with and carried out by industry. The objective of this session is an interactive discussion between you and the panelists. All of us are learning something. At the last workshop, I learned quite a lot and made a few errors, but we are learning.

I will be going through a straightforward review of the criteria and giving my own observations on those criteria.

Slide 1



WORKPLACE HAZARDOUS MATERIAL
INFORMATION SYSTEM (WHMIS)

Classification

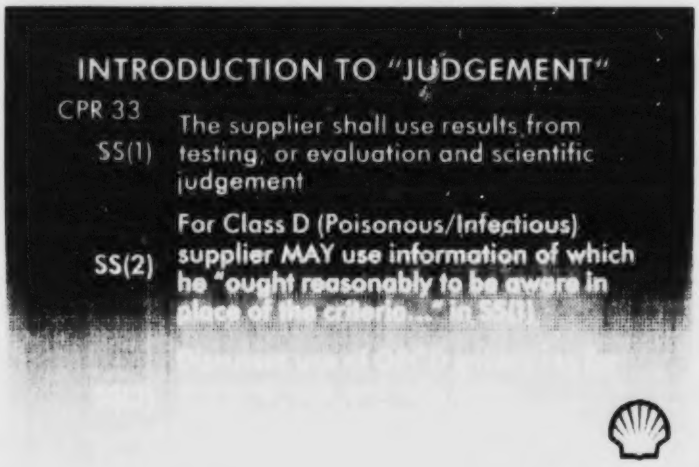
OUT

Controlled Product

MSDS – Appropriate Statements
Label – Correct Symbol
Worker Education

In theory, the classification process of WHMIS is simple to carry out. One classifies the materials; they either meet the criteria or one of the criteria, or they do not. If they do not, they fall out of WHMIS. If they are captured by at least one, that material becomes a controlled product under the Hazardous Products Act and, as a result, you will write your MSDS, do your labels, and carry out worker education.

Slide 5



INTRODUCTION TO "JUDGEMENT"

CPR 33

SS(1) The supplier shall use results from testing, or evaluation and scientific judgement

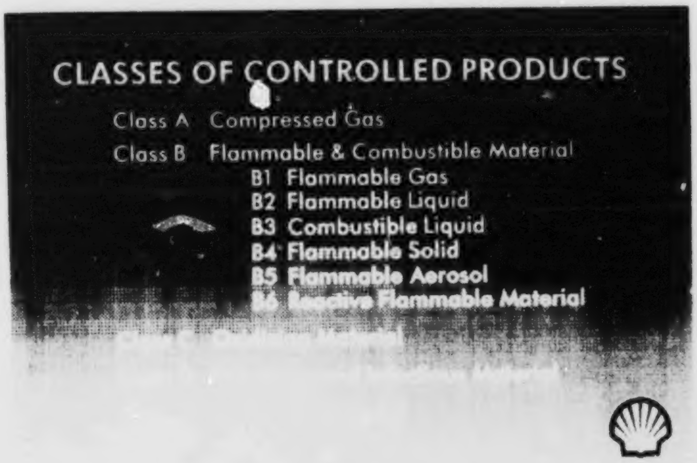
SS(2) For Class D (Poisonous/Infectious) supplier MAY use information of which he "ought reasonably to be aware in place of the criteria..." in SS(1)

First, the supplier shall use results from testing; or he shall use evaluation and scientific judgment in order to classify a material. That is in the Regulations; you will follow that requirement.

Subsection 2 deals with Class D—Poisonous/Infectious. Not only does it say that you shall use judgment, but in place of the criteria, you may use information of which you ought to be reasonably aware. You use evaluation, you use scientific judgment and, for Class D, you may also use information of which you should be aware—which does not necessarily mean evaluation or scientific judgment. It means you have to go and look. That is a problem; how far do you look? You will hear some of us today talk about the amount of time it sometimes takes to do really comprehensive evaluations.

Subsection 3 is about the OECD guidelines for test protocols, and references additional guidelines for older studies, such as the old Draize test, and Environmental Protection Agency (EPA) requirements for long-term tests. The interpretation of such studies is full of judgment because the studies may or may not meet good laboratory practices. They may or may not be up to a sufficient standard. Only you, when you do your evaluation, will decide if they are good or right enough to drive the classification process. You will be using judgment; anybody who classifies will. It is painful sometimes because you are not sure what is right.

Slide 6



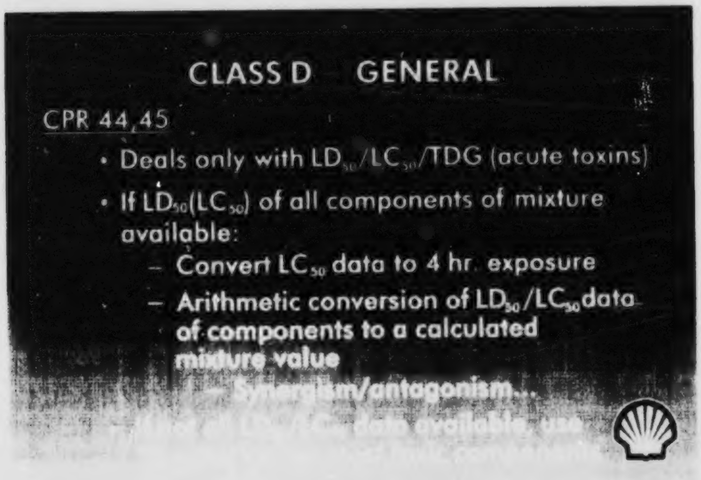
CLASSES OF CONTROLLED PRODUCTS

Class A Compressed Gas

Class B Flammable & Combustible Material
- B1 Flammable Gas
- B2 Flammable Liquid
- B3 Combustible Liquid
- B4 Flammable Solid
- B5 Flammable Aerosol
- B6 Reactive Flammable Material

You have all seen the list of six classes of controlled substances. I will spend quite a bit of time on Class D and a little time on Class E, but I am not going to talk about Classes A, B, C, and F again. Their physical hazards are relatively straightforward; you either have data or, if you need any, you should generate it. If it's not there, you can't do much about it except test. This is somewhat different from the Poisonous and Infectious Class.

Slide 7



CLASS D GENERAL

CPR 44,45
- Deals only with LD_{50}/LC_{50}/TDG (acute toxins)
- If $LD_{50}(LC_{50})$ of all components of mixture available:
  - Convert LC_{50} data to 4 hr. exposure
  - Arithmetic conversion of LD_{50}/LC_{50} data of components to a calculated mixture value
    - Synergism/antagonism...
- [illegible] data available, use

CPR 44 and 45 deal only with the acute toxicity aspects. They talk about what you will do if you have the LD_{50} or the LC_{50} of all components of mixtures. We all talk about LD_{50}s and LC_{50}s as if they are immovable numbers. In RTECS or any other basic references, you are going to find sometimes, in some of the more common materials, ten or fifteen LD_{50}s or LC_{50}s. Some people

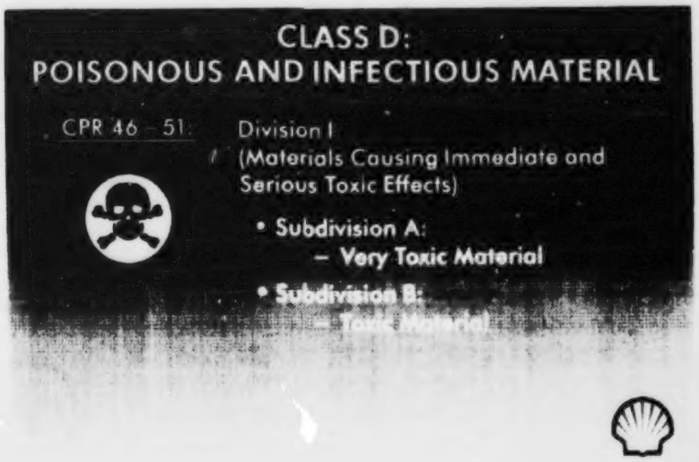
Geoff Granville *continued*

even get LC_{50}s (a lethal concentration that will kill 50%) wrong. Some people pick up the fact that fish toxicity is also given in terms of LC_{50}s; fish toxicity does not relate to this; we are talking about mammalian toxicity for the prediction of acute hazards to people. You have to determine what LD_{50} value you will use; those values can change up to around a factor of ten. Most of the time, you should use the most conservative one. But sometimes the most conservative value is a very poor one. You have to go back to the original reference and check it. Was an appropriate number of animals used? Were the investigators doing what they said they did? All these things are important even for a "simple" LD_{50}; it is often not appreciated what depth you can get into.

CPR 44, 45 talks about the doses which cause 50% lethal concentration, or 50% death; and the Transportation of Dangerous Goods aspect dealing with acute toxins. It says if you do have the LD_{50} or LC_{50} for all the components of a mixture, you can convert the LC_{50} data to four-hour exposure. It gives you a conversion factor so the lethal concentration could be converted to a four-hour exposure which is the exposure mandated for use within WHMIS. It allows you to calculate the mixtures of LD_{50} or LC_{50} as long as you have individual LD_{50} or LC_{50} for the components. I don't think you will be needing that conversion often. Most of the time, if you have individual LD_{50} values for your components, that material will be classifiable if it's a mixture based on the concentration of the component and its LD_{50}; if its LD_{50} meets one of the cut-off criteria for LD_{50} then that mixture itself will be classified. You don't have to calculate the LD_{50} or LC_{50} for the mixture, but some of you may still wish to do so. It is unlikely that our company would be doing that in any of our mixtures.

What about synergism and antagonism? What if a mixture is much more toxic than you would think in view of the individual components? I can't give you too much help on that one. If synergism or antagonism is present and you don't know about it, there is nothing you can do. We spend a lot of time worrying about synergism and antagonism; my observation is it doesn't often happen. Usually when you put two or more materials together into a mixture, the toxicity is just additive. That is what this arithmetic conversion does, it calculates the acute toxicity in an additive manner. The fears of synergism and antagonism for acute toxicity are unlikely to be a critical problem under WHMIS. If you do not have all the LD_{50} or LC_{50} data available for a mixture, then you will use the 1% criterion for mixtures.

Slide 8



CLASS D:
POISONOUS AND INFECTIOUS MATERIAL

CPR 46 - 51:

Division I
(Materials Causing Immediate and Serious Toxic Effects)

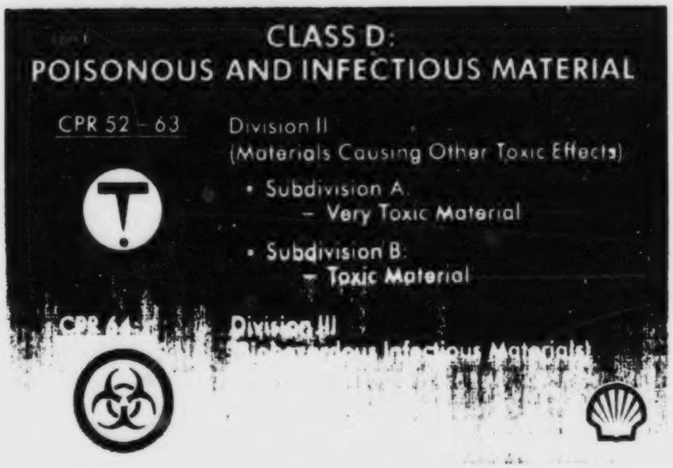
- Subdivision A:
  - Very Toxic Material
- Subdivision B:
  - Toxic Material

Under CPR Section 46-51, the actual LD_{50} or LC_{50} criteria are all given. In the slides, I include the actual symbol for the label, the difference between toxic and very toxic, Division I and Division II.

Division I is the acute. The WHMIS Criteria Working Group developed a split into Subdivisions A and B such that you have very toxic materials, which have a series of LD_{50} and LC_{50} criteria with a numerical value sufficiently low that we consider those materials of higher concern for communication of hazards; so that went into Subdivision A. Materials with quantitative and larger number or an LD_{50} 500 mg/kg fell under Class D rather than the 50 mg/kg in Subdivision A. That was done for the purpose of communicating whether a material was toxic or very toxic.

There is no difference in the actual symbol on the label. You can use the skull and crossbones. For all these materials, we are trying to communicate the fact that there is potential danger of immediate and/or lethal harm due to overexposure. You have toxic gases like cyanide or hydrogen sulphide. You have highly toxic materials like some pesticides, except they are not yet under WHMIS control. That's the rationale behind the Division I aspect, the acute toxicities. We originally didn't think there was too much judgment required under that aspect. People use LD_{50}s and LC_{50}s a lot; there are a lot of data; I now think there will be some judgment practised even there.

Slide 9



CLASS D:
POISONOUS AND INFECTIOUS MATERIAL

CPR 52 – 63

Division II
(Materials Causing Other Toxic Effects)

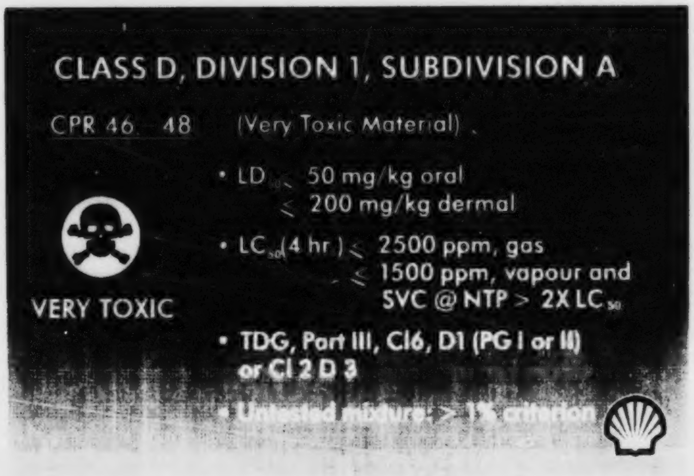
- Subdivision A:
  - Very Toxic Material
- Subdivision B:
  - Toxic Material

CPR 64

Division III
(Biohazardous Infectious Materials)

In Division II we talk about the longer term hazards. We have a new symbol—the toxic or stylized "T." Division II is subdivided again for purposes of hazard communication into Subdivision A, very toxic, and Subdivision B, toxic.

Slide 10



CLASS D, DIVISION 1, SUBDIVISION A

CPR 46 48

(Very Toxic Material)

VERY TOXIC

- $LD_{50} \leq$ 50 mg/kg oral
  $\leq$ 200 mg/kg dermal
- LC_{50}(4 hr) $\leq$ 2500 ppm, gas
  $\leq$ 1500 ppm, vapour and SVC @ NTP > 2X LC_{50}
- TDG, Part III, Cl6, D1 (PG I or II) or Cl 2 D 3
- Untested mixture > 1% criterion

The acute toxicity criteria you will be using to classify materials as very toxic or toxic are on this slide. For very toxic you have the oral LD_{50} cut-off of 50 mg/kg. When asked what species of animal you use, use whatever species for which there are data available. Most of the time, that will be the rat or mouse LD_{50} values; they are the most reliable because they are the species with the most test data. Inconsistency is likely to be reduced, but even so there will be problems. The cut-off of oral LD_{50} for very toxic material is 50 mg of that material per kilogram/body weight.

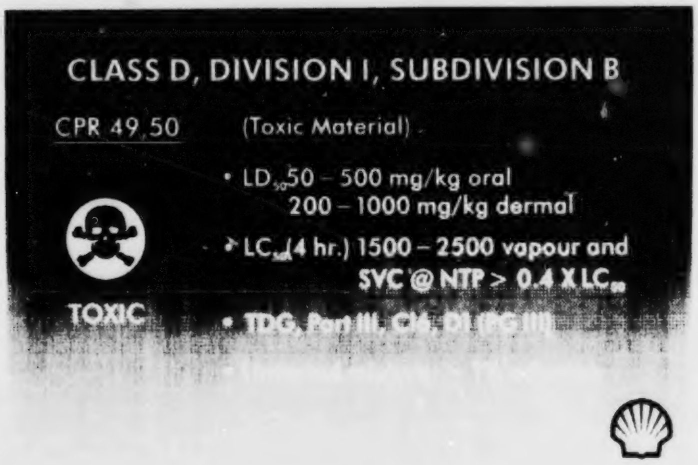
Geoff Granville *continued*

For dermal toxicity studies, if you have a 24-hour occluded test in animals and if a material is more toxic than 200 mg/kg, that again is the drive to categorize materials very toxic. For the lethal concentration aspect, the study has to be four hours in duration. If someone has done an LC_{50} study in one hour or eight hours, you can convert to four hours by the formula that is referenced in the regulations. For gases, materials with an LC_{50} of less than 25,000 parts per million, for vapours less than 15,000 ppm and saturated vapour concentration at normal temperature and pressure must be greater than two times the LC_{50}. The idea is to make sure that only materials which are likely to pose an inhalation hazard are going to be captured. Materials which are not volatile are unlikely to present a hazard under normal conditions. This is consistent with the Transportation of Dangerous Goods Act, which is important. There is not too much judgment. But remember, for materials about which a lot of acute toxicity data are known, there are a lot of LD_{50} values.

The third criterion which drives materials into CPR 46-48 is the transportation aspect. If a material is listed in the TDG (Transportation of Dangerous Goods) Part III, Class 6, Division 1, Packing Groups I or II, or Class 2 Division 3, that material will automatically go into WHMIS. You had better know your TDG booklet and know the way to go through it. It may make life a lot easier for driving the classification.

For a mixture, not a pure material (and most of the substances that we handle in industry are mixtures), the 1% criterion applies. If a mixture contains a component that has more than 1%, then the criteria will drive that mixture.

Slide 11



CLASS D, DIVISION I, SUBDIVISION B

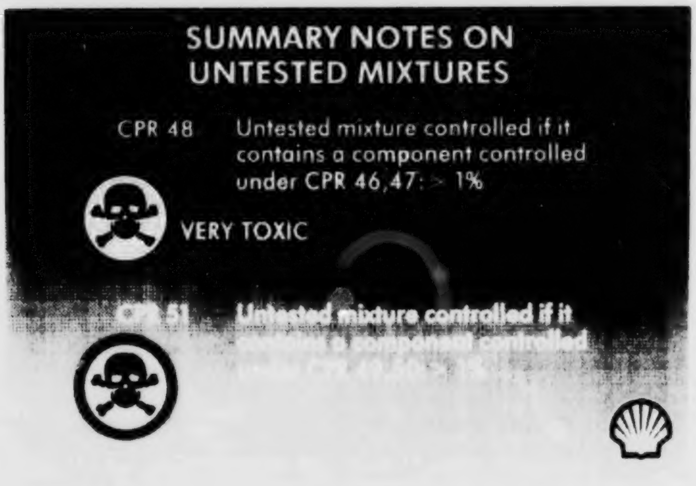
CPR 49,50 (Toxic Material)

- LD_{50} 50 – 500 mg/kg oral
  200 – 1000 mg/kg dermal
- LC_{50} (4 hr.) 1500 – 2500 vapour and
  SVC @ NTP > 0.4 X LC_{50}
- TDG, Part III, Cl6, D1 (PG III)

TOXIC

Subdivision B—Toxic Materials have the same symbol as before. The important thing for communication purposes is that these materials are not going to be as acutely toxic. The oral LC_{50} goes from 50 up to 500 mg/kg and dermal goes up by a factor of 5 to 1,000 mg/kg. The LC_{50} is also higher, and you have that other little drive about the saturated vapour concentration. Other TDG aspects are referenced. Again, there is the 1% criterion for mixtures.

Slide 12



SUMMARY NOTES ON
UNTESTED MIXTURES

CPR 48 Untested mixture controlled if it contains a component controlled under CPR 46,47: > 1%

VERY TOXIC

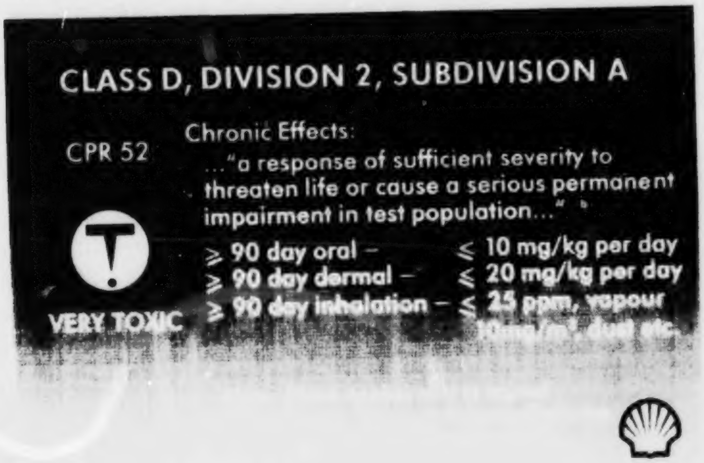
CPR 51 Untested mixture controlled if it contains a component controlled under CPR 49,50: > 1%

For untested mixtures, if you have a mixture that does not have a calculated LD_{50} or LC_{50} value, you will look at the toxicology of the components. If any of the components are present at greater than 1% and would be classified as very toxic under WHMIS under CPR 48 or 51, those materials will drive that product to be a

Geoff Granville *continued*

controlled product. That will happen quite often. There aren't too many occasions with some of the complex mixtures where you have full information. You will have to look at the data on the individual components, find a product which is present at 1% or more, check if its LD_{50} or LC_{50} values meet the criteria, and that will drive that material into a controlled product.

Slide 13



CLASS D, DIVISION 2, SUBDIVISION A

CPR 52

Chronic Effects:

..."a response of sufficient severity to threaten life or cause a serious permanent impairment in test population..."

$\geq$ 90 day oral – $\leq$ 10 mg/kg per day
$\geq$ 90 day dermal – $\leq$ 20 mg/kg per day
$\geq$ 90 day inhalation – $\leq$ 25 ppm, vapour
10 mg/m^3, dust etc.

VERY TOXIC

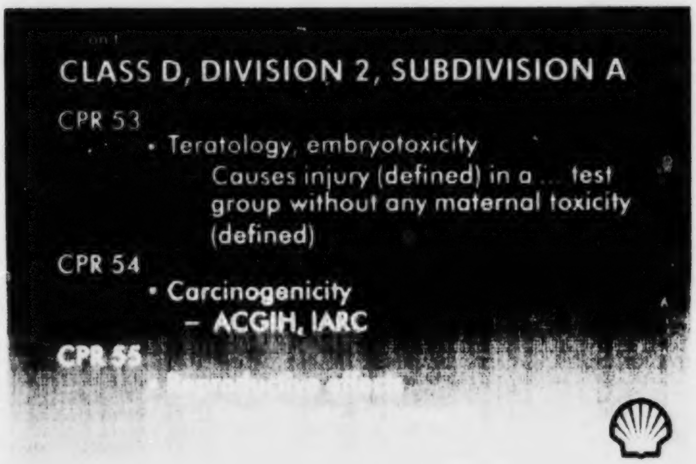
Now for Division 2 aspects, the non-acute effects. One of the first aspects that causes one's eyes to open wide, to panic, and to ask what does this mean, is the definition under chronic effects in CPR 52. A chronic effect is defined as a response of sufficient severity to threaten life or cause a serious permanent impairment in test population. Test population can include human beings but we are not actually referenced in the chronic toxicity; you will therefore generally use animal data. There is an implication that data from human beings are allowable; that is—professional judgment. If you have no animal data but you do have human information, are you not going to use it? It is not mandated in WHMIS. But you're not doing a good job on hazard communication if you don't reference known effects in human beings on your MSDS. The specific words aren't in the criteria, just the implication.

Under the chronic effects area, a series of OECD guidelines are specifically referenced for the conduct of 90-day studies, orally, dermally or by inhalation in mammalian species. Such studies have been carried out on a wide range of materials. If the studies carried out meet OECD guidelines, and if there have been effects noted orally at less than 10 mg/kg per day or dermally at 20 mg/kg per day or by inhalation at 25 ppm, vapour, 10 mg/m^3, dust etc., and

Geoff Granville *continued*

if studies carried out show effects of sufficient severity to threaten life or cause a serious permanent effect, that will drive WHMIS. There is no doubt that if you are killing animals in a 90-day study, you have a sufficiently severe effect. What about the doses—do they meet it? It's easy to look at death as an end point, but what about mild effects, such as a small amount of emphysema? It is difficult to measure in animals. What about a minor degree of skin irritation following a dermal study? A lot of these things will require judgment.

Slide 14



CLASS D, DIVISION 2, SUBDIVISION A

CPR 53
- Teratology, embryotoxicity
  Causes injury (defined) in a ... test group without any maternal toxicity (defined)

CPR 54
- Carcinogenicity
  - ACGIH, IARC

CPR 55

Chronic effects are difficult to understand. It gets even more complicated in CPR 53 which deals with teratology (the production of a malformed fetus) or embryotoxicity, which can include anything from complete resorption of an embryo (no birth at all) to change in body weight when a fetus is born. We have been looking at a number of studies on various well-known industrial chemicals which have been tested at relatively high doses but not high enough to cause any obvious maternal toxicity yet there is a slight delay in the development of the young. The animals are born a little lighter, less mature at birth. Is that embryotoxicity? Right now we are tending to think that such materials will meet the embryotoxicity requirements; but we are still evaluating that in our offices; we are not sure.

A lot of materials you know and work with every day are in that questionable area. Are they or are they not embryotoxic? The definition seems simple. If there is a study being carried out meeting the correct OECD guidelines, if that study shows there is no maternal toxicity as evidenced in a significant drop in the mother's body weight, if there are any effects on the fetus or the birth

Geoff Granville *continued*

process, that material becomes embryotoxic or teratogenic; it will become a controlled product.

Rather than set up or recommend setting up some enormous peer group that would evaluate the carcinogenicity of all materials in Canada, the WHMIS Criteria Group suggested you must look at the lists; it's easier. What has been developed in the Regulations are references to two lists: the American Conference of Governmental Industrial Hygienists (ACGIH) has a list of carcinogens; the International Agency for Research of Cancer (IARC) also has lists and ongoing evaluations of materials. Any material that meets certain parts of those lists will automatically become a WHMIS carcinogen.

The way the IARC lists are being developed now is different from the way they were done four years ago; a whole different range of materials is being included. ACGIH's way of looking at carcinogens is also different from the way of a while ago. Whenever you reference something at one period in time, you may have been correct at the time you prepared those criteria, but you may not be correct when they are being interpreted. These criteria were really developed in 1984; now in 1988, with the benefit of hindsight, there will be a few problems, but fewer problems than you would have had if we had said a carcinogen is a material that an individual decides is a carcinogen. It is a delight because it is easy to use and carcinogen regulation is usually a horrendous affair; whether it's accurate is another question.

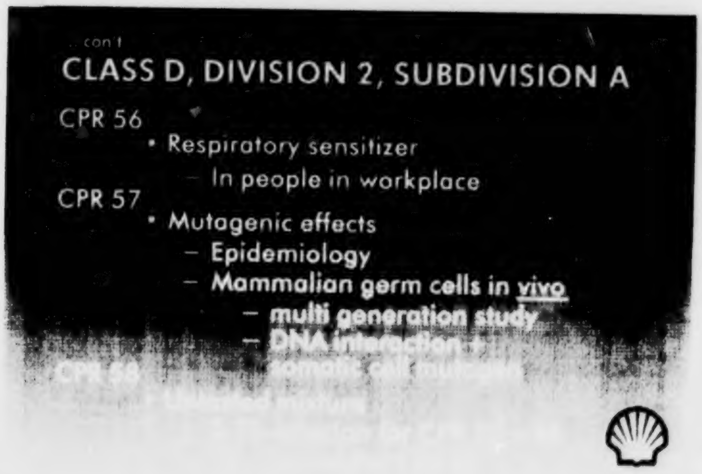
What if you have a material that you are aware has a carcinogenic study available? A material you consider to be a carcinogen according to your own company's guidelines may not yet be in IARC or ACGIH. What will you do? In theory, you do not have to communicate the hazard because the material is not yet on the list, but would you not communicate a material your company thinks is a carcinogen? A "no" answer is very unlikely. Judgment is "ought to be reasonably aware"; that has to be remembered when you are going through these specific criteria. There is more than just the criteria to use when you come to classify materials.

For CPR 55, reproductive effects do reference human beings as well as test animals. There is OECD protocol dealing with reproductive toxicity and if you demonstrate effects on reproduction in such a study, that material is automatically going to be captured, and also in human beings. This is a bit of a problem because you have no dose relationship with human beings. People can be badly overdosed using a material, such as a drug; that fact would drive that material into WHMIS. Whenever you develop a series of criteria, there are bound to be some difficulties. We do know there

Geoff Granville *continued*

are materials which have caused effects in human beings in the form of sterility. You'd want to communicate that effect.

Slide 15



...con't

CLASS D, DIVISION 2, SUBDIVISION A

CPR 56
- Respiratory sensitizer
  - In people in workplace

CPR 57
- Mutagenic effects
  - Epidemiology
  - Mammalian germ cells in vivo
    - multi generation study
    - DNA interaction + somatic cell mutagen

CPR 58

[illegible]

The material that is a respiratory sensitizer in animals or a material which is shown to cause respiratory sensitization in human beings such as the volatile isocyanates will be captured under Subdivision A of Class 2. The question is: "What about the human aspect? Was there just a single case of respiratory sensitization in the whole of literature for 50 years?" If that's the case, you may think it safe to ignore the one or two references which do not seem supportable, especially if the rest of the information you have on the product does not indicate it should be a sensitizer. That won't happen too often. The intent was to capture materials that really could cause respiratory sensitization, which can be a nasty effect. It can have a major effect in the workplace if you are dealing with a respiratory sensitizer.

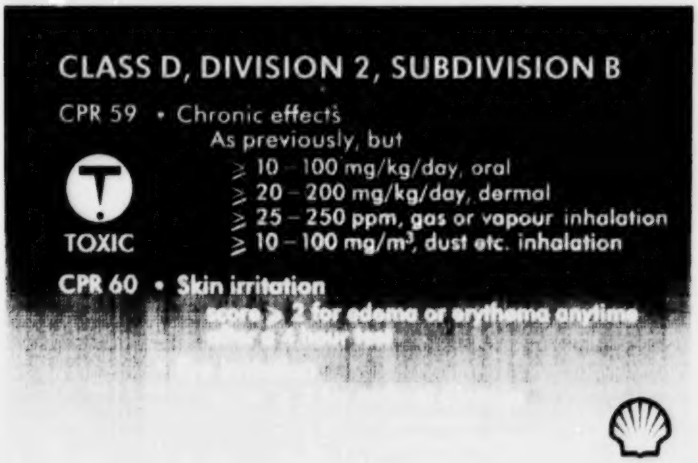
The mutagenic effect is a hard criterion to talk about. If a material is shown to be a human mutagen, epidemiological studies will be a criterion for inclusion in that class. At this time, there are no known human mutagens, no chemical mutagens at least. It is a class that is almost waiting for materials to fit into it. The mammalian aspect is about the effects on mammalian germ cells in vivo (using whole animals for the study), not in vitro techniques. The two specific criteria are for mutagens, either as evidenced in an animal study covering more than one generation (so you can see if there are any birth defects or mutagenic effects in the offspring), or evidence of interaction with cellular DNA together with knowledge that the material is known to be a somatic cell mutagen in the living animal you have tested. They're pretty

Geoff Granville *continued*

difficult and complicated. I would submit that groups like Health and Welfare Canada with their mutagenicity group may be useful if any of you have materials that you are thinking could create a problem. CCOHS will also assist on that one. Mutagenicity is a word we bandy around a lot but don't really have a good handle on; that sometimes gives us real problems in interpretation.

For untested mixtures, for materials captured under chronic toxicity, you have a 1% criterion; for all the other effects, you have the 0.1% criterion. If you have an untested mixture that contains a substance at more than 0.1% that meets any of those other criteria, that mixture will become classified as a controlled product.

Slide 16



CLASS D, DIVISION 2, SUBDIVISION B

CPR 59 • Chronic effects
As previously, but
≥ 10 – 100 mg/kg/day, oral
≥ 20 – 200 mg/kg/day, dermal
≥ 25 – 250 ppm, gas or vapour inhalation
≥ 10 – 100 mg/m³, dust etc. inhalation

TOXIC

CPR 60 • Skin irritation
score ≥ 2 for edema or erythema anytime
after a 4 hour test

For Subdivision B, there is a repetition of the chronic effects; but the referenced doses are lower. Materials which cause effects at between 10 and 100 mg/kg orally in a 90-day study or the stated doses for dermal, gas vapour, dust inhalation, will go into Class D under Subdivision B if that study meets OECD standards. There is no difference in the label or the symbol for this criterion, but there is quite a difference in the way you may present the information in an MSDS or in a training session.

Skin irritation is referenced as a specific criterion. Skin and eye irritation questions were two of the reasons why this workshop came to be held. In the literature, there are loads of references to materials causing skin irritation. Most materials used, given sufficient exposure, can easily cause irritation. That is not a function of the intrinsic toxicity; it's a function of the total exposure over a number of years. Hazard is a function of both toxicity and

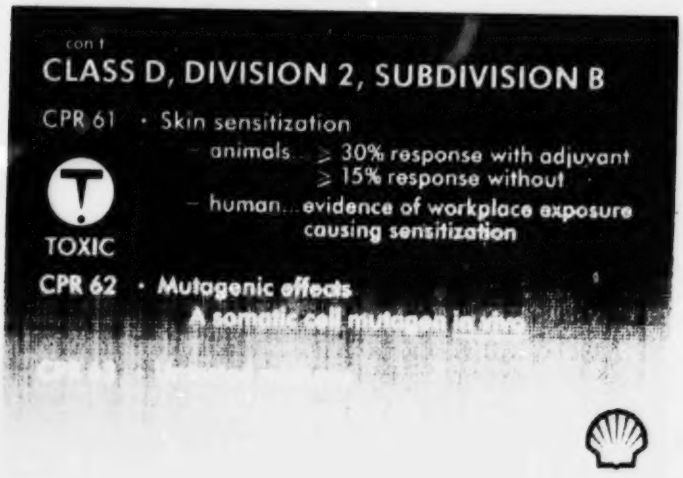
Geoff Granville *continued*

exposure. A lot of materials have been mentioned in the literature as being irritants, but they do not really cause skin irritation under the more exact meaning of the word. If everything is listed in the same way as irritant, you are not going to know the difference between a really strong irritant and a weak irritant.

So specific criteria were developed. In the study for skin irritation in animals, if you have a score of 2 or more for certain end points, redness or swelling in a certain study, that material will be classified as an irritant. Some of the common solvents are not irritating under those test guidelines, but given prolonged repeated contact, they can cause dermatitis. The latter material will not be classified as an irritant, but if you have information on human beings you will mention that somehow. Human data do not drive the process to classify a material as an irritant. Otherwise, because people handle solvents for weeks and years, everything would end up as an irritant which is just as bad as having no hazard communication at all.

There is also eye irritation. There are specific studies which are carried out to investigate the degree of eye irritancy. If materials score greater than certain given values, the material will be classified as an eye irritant.

Slide 17



con't

CLASS D, DIVISION 2, SUBDIVISION B

CPR 61 · Skin sensitization
- animals ... $\geq$ 30% response with adjuvant
  $\geq$ 15% response without
- human ... evidence of workplace exposure causing sensitization

TOXIC

CPR 62 · Mutagenic effects

A somatic cell mutagen in vivo

Skin sensitization is quite difficult to classify for, because you have to go back to the original reference. In a study in which you deliberately "pep" up the immune system in guinea pigs by giving them an adjuvant (an injection of dead bacteria which develops the immune response in those guinea pigs to a higher level) and you then measure a response greater than 30%, that material is classified as a skin sensitizer. If you do a study which does not

Geoff Granville *continued*

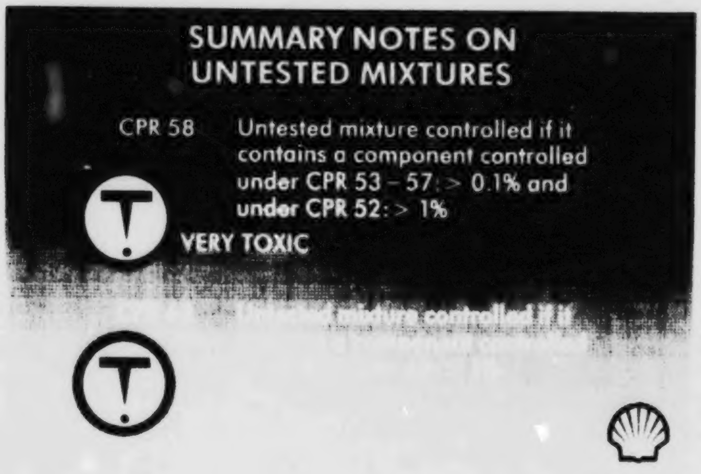
use an adjuvant, then a 15% response results in classification. This value of 15% is a bit of a problem. In most of the older studies, people used 10 guinea pigs to measure skin sensitization. It is hard to get a response of 1.5 guinea pigs; if you have a response in two guinea pigs then that material would be captured. So it takes time, but is quite easy to investigate if you go back to the original reference and know how to understand it.

The human criterion for sensitization is more of a problem. It talks about evidence of workplace exposure causing sensitization. Most materials can cause skin sensitization in some people somewhere. Really strong sensitizers cause sensitization in a lot of people given overexposure; they are quite easy to reference. But well known materials like isopropyl alcohol have been mentioned once or twice as causing sensitization in some people. That is a very rare effect. Our company sells isopropyl alcohol. We are not going to be capturing IPA under human sensitization even though there do exist a couple of references. We know that IPA is not a sensitization hazard; all the studies carried out show it isn't, it's just that one or two people in this world have been sensitized to it. We are using judgment to say that IPA should not be classified as a sensitizer. Of course, valid sensitizers should be communicated as a hazard.

Back to mutagenicity again—a material that causes mutation in a live animal study without evidence of hitting germ cell DNA will be captured under toxic criterion—CPR 62, as distinguished from the criterion that you have concern may be a mutagen. It is a lower degree of hazard.

CPR 63 is about the untested mixture. Any pure material in any of those classes if it is a mixture of more than 1%, will make that whole mixture a controlled product. The whole aspect is complicated and a bit of judgment is used.

Slide 18



SUMMARY NOTES ON UNTESTED MIXTURES

CPR 58 Untested mixture controlled if it contains a component controlled under CPR 53 – 57: > 0.1% and under CPR 52: > 1%

VERY TOXIC

Untested mixture controlled if it

To summarize Division 2, all materials that are present at 0.1% or 1% in a mixture will drive that material as being a controlled product.

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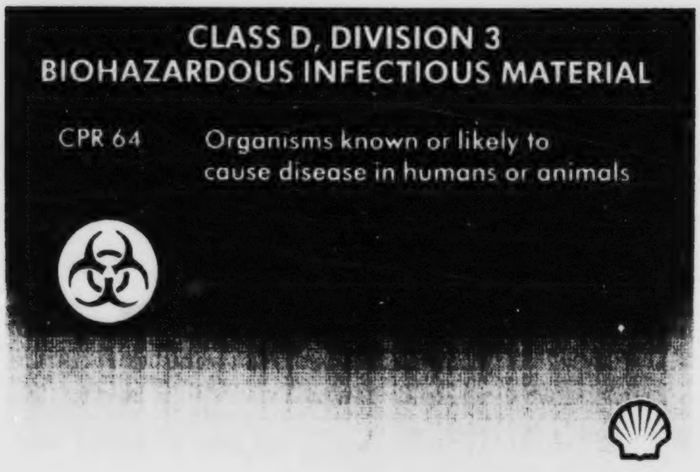
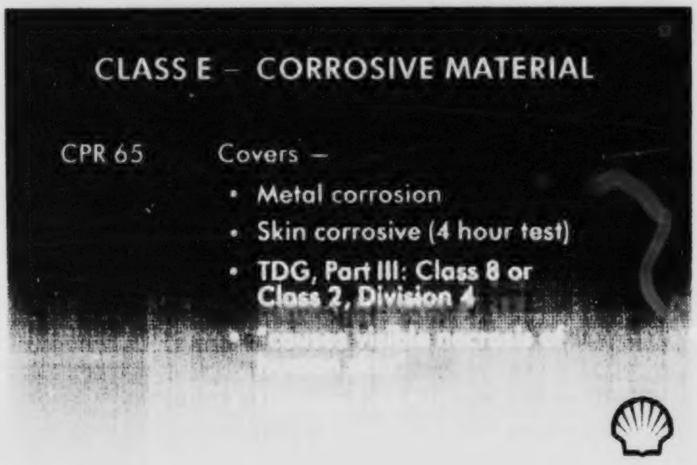


CLASS D, DIVISION 3 BIOHAZARDOUS INFECTIOUS MATERIAL

CPR 64 Organisms known or likely to cause disease in humans or animals

To complete Class D, you have to talk about biohazardous infectious materials. The materials you are trying to cover are some of the bacteria, the viruses that can be transported and used in the laboratories. These are not a major problem to most industries; but, for example, in dairy production where moulds may be used and in hospitals and research labs that use infectious materials, people are going to have to look into that in some detail. Guidelines are being developed and will be out in the next two or three months.

Slide 20



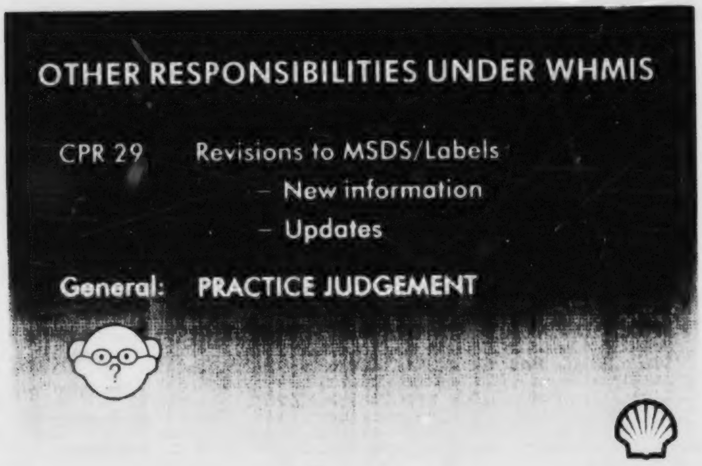
CLASS E – CORROSIVE MATERIAL

CPR 65 Covers –

- Metal corrosion
- Skin corrosive (4 hour test)
- TDG, Part III: Class 8 or Class 2, Division 4
- Causes visible necrosis of

CPR 65, the Corrosive Material Class, covers corrosion to metal, which is straightforward to measure if you can find the information. It also covers a four-hour test, an OECD study; if a material in a four-hour test has been shown to cause corrosion, that material is corrosive. It also includes the TDG aspects for corrosive materials. Materials that have been shown to cause visible necrosis of human skin will be classified. If a mixture has not been tested and it contains a corrosive of more than 1%, that corrosive will drive the whole mixture to be controlled.

Slide 21



OTHER RESPONSIBILITIES UNDER WHMIS

CPR 29 Revisions to MSDS/Labels
- New information
- Updates

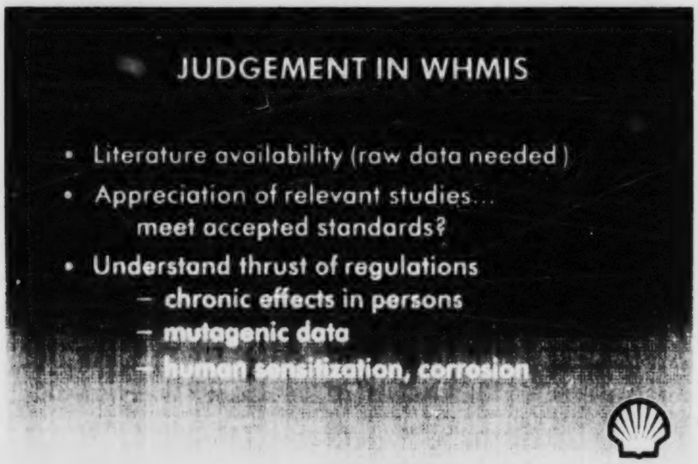
General: PRACTICE JUDGEMENT

The only other responsibility under WHMIS which is relevant here is CPR 29 which deals with when to revise an MSDS or revise a label. By law, you will have to revise MSDSs every third year. Within that period of time, there may well be new information

Geoff Granville *continued*

which could be important. It will be your judgment whether the new information is of sufficient importance to require a revision to an MSDS, an update of labels or both. If it's information that would drive a material into being a controlled product for another category, then it is important. But if you already have the material captured as a chronic hazard and a bit more chronic information comes out, do you want to change your MSDS? That is judgment; you will have to decide if you feel it is important enough to communicate. Judgment is most important in this, and judgment is difficult to mandate even though it is mentioned in WHMIS.

Slide 22



JUDGEMENT IN WHMIS

- Literature availability (raw data needed)
- Appreciation of relevant studies...
  meet accepted standards?
- Understand thrust of regulations
  - chronic effects in persons
  - mutagenic data
  - human sensitization, corrosion

By judgment we mean "what literature are you going to use?" You can't just look at volumes like RTECS, which is a huge compendium of summary information put together in a poorly reviewed fashion, where the peer review process was not good, and where a lot of the work was carried out by students with no supervision, 10 or 15 years ago. Use that information at your peril. The most important use of RTECS is as a first source of information; then you need to go back to the references. That could make the job of classification for some materials complex and slow. If you are a small company and you don't have the resources or the knowledge to go too far, that's one thing. If you are a large company and decide you can't be bothered, that's something different. How far you actually go into literature is a matter of judgment.

We have been looking at some petroleum mixtures in the last few weeks, and are spending weeks going back to raw data finding references from unpublished sources in the US and we cannot go much further. We are not feeling comfortable at stopping at any one point because we know there is another piece of paper somewhere.

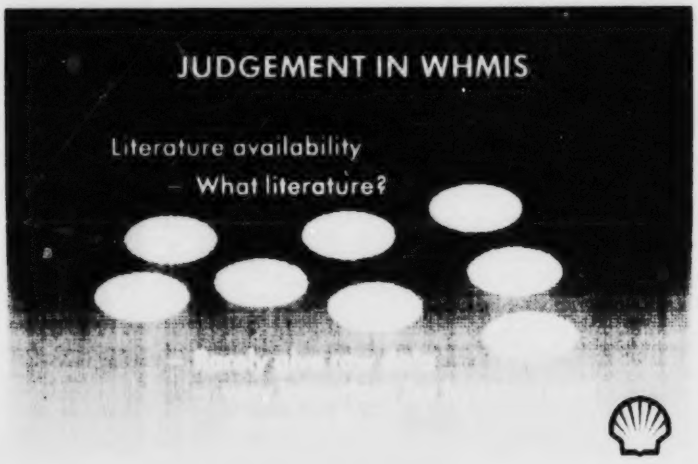
Geoff Granville *continued*

When you get the data, how good is that information? One has to appreciate whether the study is relevant. Does it meet accepted standards? Does a study carried out 30 years ago, which you know would not meet currently accepted standards, nevertheless look good? Was it a study carried out under the best judgment of the times? Is it a study that still looks good? Some studies, dating back to the 1920s and 1930s are of better quality than some studies I see coming out this year; the problem is how it relates to modern requirements. The important thing is to understand the thrust of the regulations. Human beings are not referenced in specific chronic criteria even though they are included in one part of the Regulations. You can't say effects in human beings are excluded but there are no criteria that will say how to include chronic human effects in the classification process. It may be appropriate to reference that information in an MSDS without using it to drive the classification process.

Mutagenicity data are always complex and will continue to be so. Materials that are likely or potentially mutagenic at relatively low doses should have the hazard communicated. Materials which have a single Ames Study will not drive the classification process. You may wish to include the result of an Ames Test in an MSDS, but there is no drive to do so.

There are no quantitative criteria for human sensitization and human corrosion; if a material has caused human sensitization or corrosion that is a drive to put it into WHMIS. Sometimes you can have a tremendous overexposure in human beings; somebody could fall into a vat of a material and the report in the years to come would say there was corrosion. Is that a relevant study? That's for you to consider; you can get guidelines, but you can't get a direct answer.

Slide 23

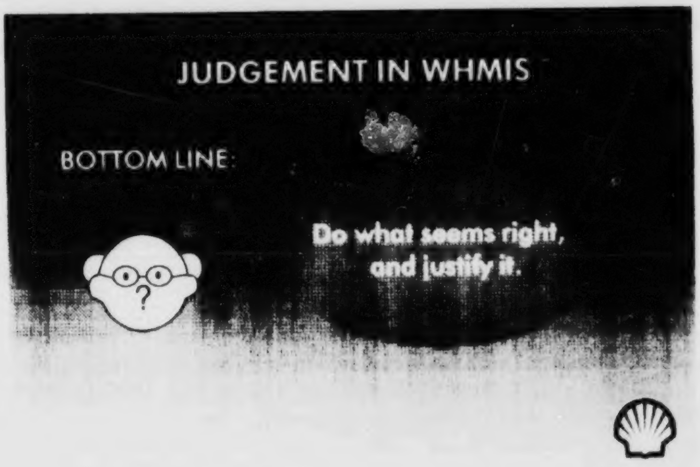


JUDGEMENT IN WHMIS

Literature availability
– What literature?

Judgment is also present in what literature you use. Everybody will be looking to the Canadian Centre with their background for information and at the Transportation of Dangerous Goods. Most people will be looking at RTECS. Everybody will have to be looking at the IARC and ACGIH lists of carcinogens, without which you can't classify materials. Some people may buy Patty, one of the more famous books in industrial hygiene and toxicology; but together all of Patty is going to set you back over $600—a lot of money for a small company to pay for a volume that will be out of date in a couple of years. You may also use test data; not many will go for test data because this information is not mandated in WHMIS for biological hazards; you do not have to test for toxicology. Apart from test data, the sources rarely give you the raw information; they are summaries and because they are summaries, they may not be good enough to drive the classification process; only you will be able to know that when you are going through your individual materials. The summaries have been used in the past as if they were almost sources of raw information for irritancy and long-term effects and yet they are not quantitative enough to be used under WHMIS.

Slide 24



JUDGEMENT IN WHMIS

BOTTOM LINE:

Do what seems right,
and justify it.

The bottom line of this whole thing is judgment. We, and most of the companies I have talked to, are going to do what we think is right. The questions is "Can we justify what we are doing?" If the answer is "yes," that's what you should do. Rarely, that will mean you can pull materials out of classification because you don't think it's appropriate. Often, you may put materials into classification because you are not 100% sure that they should not be so classified. Within every group, there will be a judgment process and it is up to you to do what you think is proper and then justify it. We are going to be driven a bit by the enforcement and the compliance aspects. If an inspector doesn't like what you do, the only thing you can do is say "This is why we did it; does it not seem right?" So justify; write down what you're doing and why you're doing it; that would be the best way, as of 1988, to try helping us for the first couple of years of WHMIS.

I hope this gave you a background to the classification process in WHMIS. It talks about judgment; it mentions the problems that you don't immediately realize are there until you start going through the process. I hope it set the scene as to what we will be doing for the rest of the day.

Robert Whiting

All of us working on classification have realized that judgment is a major part of the process. The best way to illustrate some of the problems that arise in applying judgment to the criteria is to look at a few examples. There will be discussion of particular areas of judgment and evaluation in the sessions later in the day; we could, at this stage, ask a few general questions from the panelists or the audience.

Erich Krayer
Hoechst Canada Inc

Geoff, I am a bit concerned about your last comment. Are you suggesting that we have to build a case for ourselves to justify in writing how we arrived at a certain classification? Must we look over our shoulders for the lawyers behind us? Will we find ourselves standing in front of a judge three years down the road when there has been a change in personnel and it's hazy and difficult to recreate how somebody else's judgment led to a situation which is now being questioned? This will generate a tremendous amount of documentation and memo writing. Is it necessary?

Geoff Granville

I can't answer that for everybody but what we will be doing is documenting why we have come to certain decisions on classification for any contentious products. We will not go as far as most US companies are going with full documentation and justification for all their decisions. We're not documenting out of fear of litigation but also because we are not quite sure where professional judgment stops and where answers begin. When people change places and jobs, it's sometimes difficult to explain how something was decided years ago.

We have difficulty in the area of embryotoxicity in a couple of products that you and I know and use quite regularly. We are not sure, but we will have to make a judgment call that this material is embryotoxic or not. I am sure that other companies that sell the same product will answer differently. I don't know who's right or wrong; I don't think there is a right or wrong. It's an independent judgment process. When you come down to justification, you can talk to people and justify it that way; those people can be customers, other suppliers, or governments. When you look back at a decision, you may think you should have decided something different; that's the learning process. In answer to your question—yes, we are worried about that. We want to make sure we know why we've done what we've done and if we make a mistake, be able to rectify it later. We hope we will improve the way we classify our materials under WHMIS. It won't happen by October 31; it will take a few years before we are comfortable that things are classified properly.

Erich Krayer

We have comments from the US that we should get lawyers involved in the process of the wording of the Material Safety Data Sheet and the wording of this documentation. Are you suggesting that we should be doing that?

Geoff Granville

I can't suggest what you should do; I can only speak of our own experience. No, we are not involving lawyers in the process. We think it is a scientific and technical endeavour to communicate hazards to the workplace. We don't think it's a legal exercise. The US has a different series of requirements. We want to do a good job for technical reasons and there is a reality of inspection enforcement, but that is not the main reason for it. We just want to do a good job and be consistent in our approach.

I hope other people are doing what we are doing. If you get one company that gets lawyers involved in producing legal documents, it creates a lot of pressure on everybody else. That's why these workshops are very important; to try to gain fairness and consistency.

Robert Whiting

Our experience in compiling our CHEMINFO database is that we have to document the rationale for the classification. Because WHMIS has made the system more complicated, we want to have an information source in which any one of our users can look at the classification and know why it was done. Even a few lines of explanation on how the evaluation was done should be enough. It's not necessary to write a complete legal document.

Victor Lopez
Office of the Fire Marshall of Ontario

You seem to indicate that consulting those readily available literature sources may not be sufficient—that people may have to go to regional papers. Knowing the number of small businesses there are throughout the country, how realistic is it to expect the small business to have the resources, the time and the knowledge to go beyond those readily available sources?

Geoff Granville

Most of the time, smaller companies do not make new chemicals; they are making mixtures and blending. As a result, they have to trust their suppliers. WHMIS is supplier-driven and if the supplier does the proper job, the customer should not need to classify. S/He needs to know the mixture criteria for cutoff, but that's about it.

How far can a smaller company go? You are absolutely right; you can't expect small companies to have a permanent health and safety officer for six people. I can't say how much is reasonable; each company must decide an appropriate level of care and control.

Geoff Granville *continued*

We are all living under the whole series of health and safety acts; WHMIS is just an addendum to an OH&S Act. It's a pretty significant one, but it is just an addition to what you should be doing. It helps the communication process of safety hazards. Small companies go further, but not to raw references. That is what the Canadian Centre for Occupational Health and Safety and provincial and federal government departments are here for.

Victor Lopez

Are there services a small company could use that would help them prepare that kind of documentation?

Robert Whiting

The Centre, through its inquiry service, is set up to answer questions about basic properties and hazards of chemicals through our CHEMINFO database. We are building a bank of information on all of the common industrial chemicals, including the classification according to the evaluations of the information that is available to us. For chemicals which are not in our data bank already, we are quite happy to provide information packages.

There are private consultants who are ready and willing to write data sheets, and of course, the supplier information is often a major source of information for use by the small employer who may be bringing products in. With the information sources available from the provincial governments and from the Centre, the small employer need not be left out in the cold. There is information available; and there are some very good data books, such as the NFPA books, which provide good quality summarized information.

Alan Wright
Canada Colors & Chemicals Ltd

How do you define a mixture? I'm dealing with materials that are encapsulated in solid polymers and I don't think they are hazardous, but they're in your hazardous list. When they're encapsulated they seem to be perfectly safe. They are a mixture, and yet they're encapsulated in a solid.

Robert Whiting

There will be opportunity for a discussion of this question in the session on Articles. It is not a simple topic because of the question of whether the material is in intermediate or final form.

Don Macaulay
PRC Canada Inc

I think it's ironic that unless you are producing new chemicals, you really have to depend on your suppliers. We blend chemicals and we have a number of products, and what we're finding is that the information is not available on our supplier MSDSs, yet we have the same deadline as everybody else. We are working as best we can, but I wanted to make that comment.

Geoff, you mentioned trying to establish an LD_{50} for a mixture by doing a calculation based on concentrations. You virtually dismissed that. I'm of the opinion that the calculation really doesn't do anything. You can perhaps establish an LD_{50} for your mixture, but because it's a mixture and you haven't tested it, you still have to report everything and list all the ingredients. Is that your reason or can you expand further on that?

Geoff Granville

That's just about the reason. It's a waste of time. If you have, for example, a three-component mixture; all are present at more than 1% by weight; if any one of those components is captured by the acute toxicity criteria, that mixture is automatically controlled. You don't have to calculate a mixture. But you may want to, just to show that the material is not controlled by any of the three components falling outside. If you haven't done an LD_{50} or an LC_{50} on that mixture, you are going to be reporting everything. The only way to get out of that one is to actually do an LD_{50} study. You may want to try to test your material out of WHMIS.

Don Macaulay

That's the conclusion that I reached on my own. If you have something that is 60% filler and 38% resin and 2% solvent, the solvent in it overrides anything else. For example, try to find LD_{50} data on calcium carbonate—it can't be found. Unless you test the whole mixture, you have to rate it according to the solvent that it contains.

Robert Whiting

It might be worthwhile to bring out an historical note about the calculation of LD_{50}, which is derived from the Transportation of Dangerous Goods Regulation. It does not have the per cent cutoffs as part of its criteria system, so that you can calculate the LD_{50} of the mixture knowing the LD_{50}s of the components and that would be used in the classification of your product overall.

Robert Whiting *continued*

The criteria working group felt that it would be very difficult for most non-technical people, such as small employers, to apply this kind of rule. Often the data wouldn't be available. For the sake of consistency with the United States, which uses the cutoff rule of 1% and 0.1%, it decided to use these cutoffs. There is a redundancy built into the system, and it seems that the cutoff rules would take precedence because they are more stringent.

Richard Morris

I have been involved with Consumer and Corporate Affairs in developing the regulations and more recently trying to thrash out some of the interpretations of the regulations. Through our discussions, we have been trying to iron out how someone might use the formula. The way the Controlled Products Regulations are written, Section 45, which gives the formula for using LD_{50} and LC_{50} data, comes ahead of Subsection 3 which says you can actually test the mixture. Subsection 2 talks about another aspect of using LD_{50}s and LC_{50}s and finally when you're dealing with untested mixtures, that comes even further along in the regulations. So from the point of view of interpretation, it gives the reader the impression that you use the formula first if you have all the data. If you don't have all the data, you could test the mixture. And then, if all else fails, you could use the cutoff which is 1%.

One of the concerns we have is that there are problems in using the formula. You end up with a calculated LD_{50} LC_{50} which may not bear a lot of relation to an actual tested value. It may be out by an order of magnitude. Certain health professionals have had difficulty accepting the use of a formula. But the way the regulations were written, the approach was to try tying in to TDG. If you've used the formula in TDG, then you could use it for WHMIS. It's not so much the order of precedence as it appears to be in the regulations, but if you do have all the data, you could use it to bring the material out of the WHMIS requirements if it doesn't fall into any other hazard class. You could legitimately do that because it's in the regulations, even if it meets the 1% cutoff. It will override Section 48 and the subsequent section for untested mixtures. I don't think this will be used that often because, for many substances, there is some piece of raw data lacking.

If you are working with something such as calcium carbonate where you have no doubt that the LD_{50} would be several grams per kilogram body weight, you really don't need the precise number. The corresponding number in the formula will be so absurdly small that it won't contribute. This will have to be worked out in more detail in the interpretation.

Sylvie McAuley
Travis Chemicals Inc

If our suppliers state a certain classification for a product, can we accept that as the final classification? To what extent are we responsible to research that classification and make sure it's correct? An example is Isopropyl Alcohol. I would classify it as a skin sensitizer because it is mentioned in Patty. Shell is our supplier and they say it is not a skin sensitizer. To what extent am I responsible legally to accept that classification?

I have another question about the Ingredient Disclosure List. Ethylene glycol and triethylene glycol are mentioned in the list, but diethylene glycol is not. If we do have triethylene glycol in a controlled mixture, I have to mention it, yet I'm not sure how to classify it because it doesn't fall into any classification according to WHMIS. What do I do in such a situation where I have to mention the product and yet I don't know what the classification is? I think CCOHS also has classified it as non-hazardous. Why is it in the list and what do you do when you put it down?

The third question deals with the LD_{50} of water. If I have a mixture containing water and methanol, and the concentration of methanol is just above 1%, the LD_{50} of that overall mixture would probably not be hazardous. How do I calculate that?

Geoff Granville

The first question dealing with IPA as a skin sensitizer is a perfect example of using professional judgment. There is a Patty reference, but go back to the raw material and you will find that there were two people in the study mentioned as sensitizers. There is a publication that came out in 1980 about water being a sensitizer. It causes a disease called aquagenic pruritis. It has affected three or four people in the world. Does that mean you list water as a sensitizer all the time? That's when professional judgment has a real role. IPA is a perfect example of it. No, IPA is not a likely sensitizer. There are thousands of people occupationally exposed to it and they have never come down with sensitization reactions.

What you do with your supplier's MSDS is your concern, but the way we would interpret WHMIS is that you are allowed to use your suppliers' interpretations unless you have very good reason for thinking them wrong. If you think that the material really is a sensitizer and that you were missing the requirements of WHMIS by not communicating it, then you can rewrite our MSDS into your own company's MSDS. But you have no requirement to go through the MSDS and check it for accuracy. As a large company you may wish to do that; as a small company, you wouldn't have the ability to do it. It depends on your size and competence. If

Geoff Granville *continued*

you see something in the MSDS that is obviously wrong, then you must obviously go into it. Otherwise, it is the supplier's responsibility.

Robert Whiting

A supplier must be able to justify the information s/he gives. You should understand what your supplier has said and feel comfortable with it. If you don't feel comfortable, then you will have to use your judgment in accepting or reworking the judgment that came with the supplier's data sheet. But you have to be able to justify it because that's the ultimate test in communicating hazards in the workplace; you have to communicate a level of confidence to the worker.

Geoff Granville

The second question dealt with the Ingredient Disclosure List. Remember, IDL is not a classification tool. If you have a material or mixture which is going to be a controlled product for other reasons, then anything it contains on the IDL will have to be communicated. So the IDL shouldn't be used in any way as a classification medium and the concentration cutoffs in it should mean nothing. They were just numbers, you listen to them, but the rationale behind them is irrelevant. So for something like diethylene glycol, you have a mixture of materials which includes DEG, you will put down DEG in your ingredient disclosure. But the fact that you have no data on it is irrelevant. There are hundreds of cases like that where you are disclosing information and you're wondering "Why?" To get the communication process going, you have to go to that extreme. The alternative, of course, is to test the mixture.

The third question deals with methanol and water. In a sense, if you have a binary mixture of methanol and water, and as a controlled product it contains more than 1% methanol, you don't have to worry about the mixture's LD_{50}; it is going to be classified. If you want to test that mixture of methanol and water, you can. You'll have an LD_{50} that will fall outside the acute toxins criteria. You are still going to capture that mixture for other reasons such as the long term effects of methanol. You are going to communicate those other things in the mixture anyway, so I wouldn't worry what to do for a mixture LD_{50}; don't bother to calculate it. Just put down the LD_{50} of methanol and leave a gap for water.

Application of Criteria for Skin and Eye Irritation

Presenter: Richard Morris
Chairman: Geoff Granville

Lillian Vine

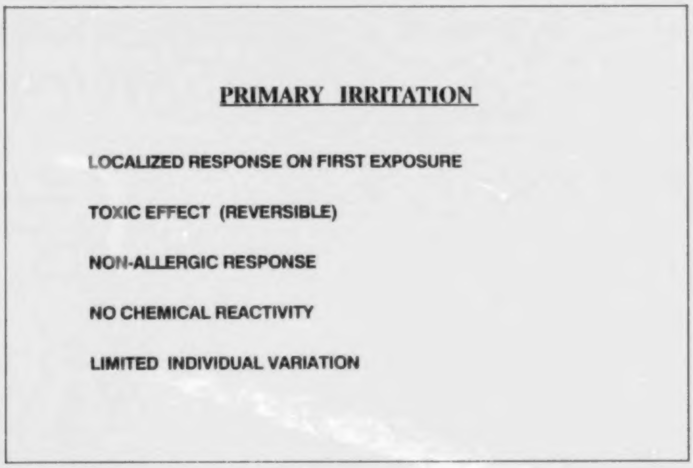
The next panelist is Richard Morris, who will be talking about skin and eye irritation. Richard was born and raised in Vancouver, did his undergraduate work in British Columbia and Alberta and graduated with a Bachelor of Science degree from the University of Alberta in Edmonton in 1963. He then did graduate work in physiology at the University of Alaska and obtained his PhD in Christchurch, New Zealand. He worked at Huntingdon Research Centre in England in toxicology and industrial hygiene during the mid-1970s. After that he taught toxicology and pharmacology at Howard University Medical School in Washington, DC, for several years before returning to Canada in 1981 to work for the Department of National Health and Welfare, Environmental and Occupational Toxicology Division. For the past seven years, Richard Morris has been a toxicologist and health advisor at Health and Welfare Canada. During the last five years, his duties have included the WHMIS project, initially as Chairman for the Criteria Working Group and subsequently as the federal advisor on WHMIS classification and related matters. He is here to share some of this vast knowledge.

Richard Morris

I am from Health and Welfare Canada, but I am here today as a person who has been involved with WHMIS for a long time and as a toxicologist.

One of the questions that might occur to somebody is why, out of all the different criteria, are we looking at skin and eye irritation? There are two reasons. First, it provides a general example of classification using a particular toxic end point. Second, there are a number of specific concerns that are related to this toxic end point.

Slide 25



PRIMARY IRRITATION

LOCALIZED RESPONSE ON FIRST EXPOSURE

TOXIC EFFECT (REVERSIBLE)

NON-ALLERGIC RESPONSE

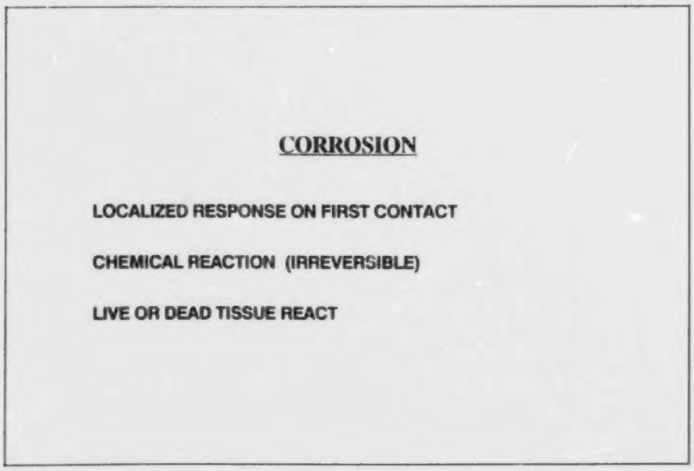
NO CHEMICAL REACTIVITY

LIMITED INDIVIDUAL VARIATION

The first question that I want to address relates to how this particular toxic effect, irritation, differs from other effects such as corrosion and sensitization. It's important to get this clear before we get into the criteria and methodology.

Primary irritation, as it is used in toxicology, is a local response that occurs generally on the first exposure. It is a toxic effect, and it's reversible. That is, when you take the material away, the effect should eventually leave. It is a non-allergic response, unlike sensitization. It shouldn't involve chemical reactivity (this will come up in our discussions about corrosion). And there is limited individual variation as to the response.

Slide 26



CORROSION

LOCALIZED RESPONSE ON FIRST CONTACT

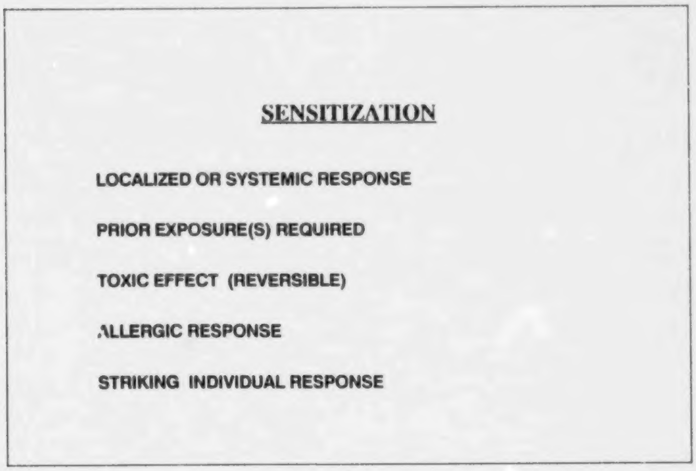
CHEMICAL REACTION (IRREVERSIBLE)

LIVE OR DEAD TISSUE REACT

Richard Morris *continued*

Slide 26 deals with corrosion and we see that there are some differences. Again, it is a localized response on the first contact, but it is a chemical reaction. It is normally described as an irreversible effect. In other words, it is a chemical reaction that takes place between the particular chemical and some component of the biological tissue. For this reason, it doesn't require an intact circulatory system or an intact animal to demonstrate it, even though the test for corrosion generally does involve animal skin. The fact is that live or dead skin would react similarly.

Slide 27



SENSITIZATION

LOCALIZED OR SYSTEMIC RESPONSE

PRIOR EXPOSURE(S) REQUIRED

TOXIC EFFECT (REVERSIBLE)

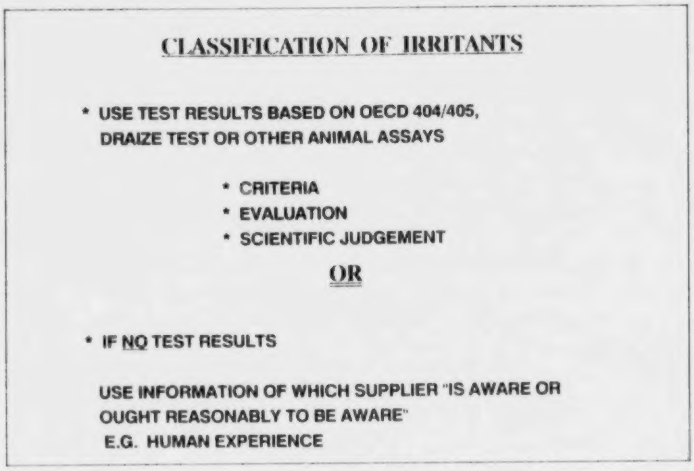
ALLERGIC RESPONSE

STRIKING INDIVIDUAL RESPONSE

Slide 27 briefly describes sensitization. It is important to realize that sensitization can be either a local effect, that is, it can occur at the site at which the exposure occurred, or it can occur somewhere else in the organism (or the person). But in all cases, prior exposure or exposures are required for the reaction to occur. Again it is a toxic effect, which is reversible if the sensitizer is removed. But once you are sensitized, you're probably always going to be sensitized. Unlike irritation, it is an allergic response. There are striking individual differences in the response. It is an idiosyncratic type of response and generally there are only a few workers that would exhibit it under very similar exposure situations.

I would like to deal now with what the Controlled Products Regulations criteria dealing with skin and eye irritation say about the classification of irritants.

Slide 28



CLASSIFICATION OF IRRITANTS

- USE TEST RESULTS BASED ON OECD 404/405, DRAIZE TEST OR OTHER ANIMAL ASSAYS
  - CRITERIA
  - EVALUATION
  - SCIENTIFIC JUDGEMENT

OR

- IF NO TEST RESULTS

USE INFORMATION OF WHICH SUPPLIER "IS AWARE OR OUGHT REASONABLY TO BE AWARE"
E.G. HUMAN EXPERIENCE

It is important when carrying out the classification of materials to know the Controlled Products Regulations (CPR). Don't work from what you've heard or what you think they say. You have to go to the Regulations and you have to try to understand their application. Certain words in the CPR text are underlined for emphasis. "The supplier shall use...results from testing that he has carried out..." These would normally be according to OECD test guidelines, in this case 404 and 405 which deal with skin and eye irritation/corrosion, or a Draize test, or any other animal assay that was carried out if it was carried out under "generally accepted standards of good scientific practice at the time." And you shall use the criteria, you shall use evaluation of those data, and you shall use scientific or professional judgment. That is what the regulations say.

Or, if you have no test results (tests are not mandated in WHMIS, particularly for toxic end points) then "you shall use information of which you are aware or ought reasonably to be aware." This last statement has had some real implications, as we'll see. This is where, for the most part, human experience fits into the classification process. The first subsection refers to test results and criteria which, in most cases, deal with specific OECD test guidelines or to animal assays. There are some exceptions.

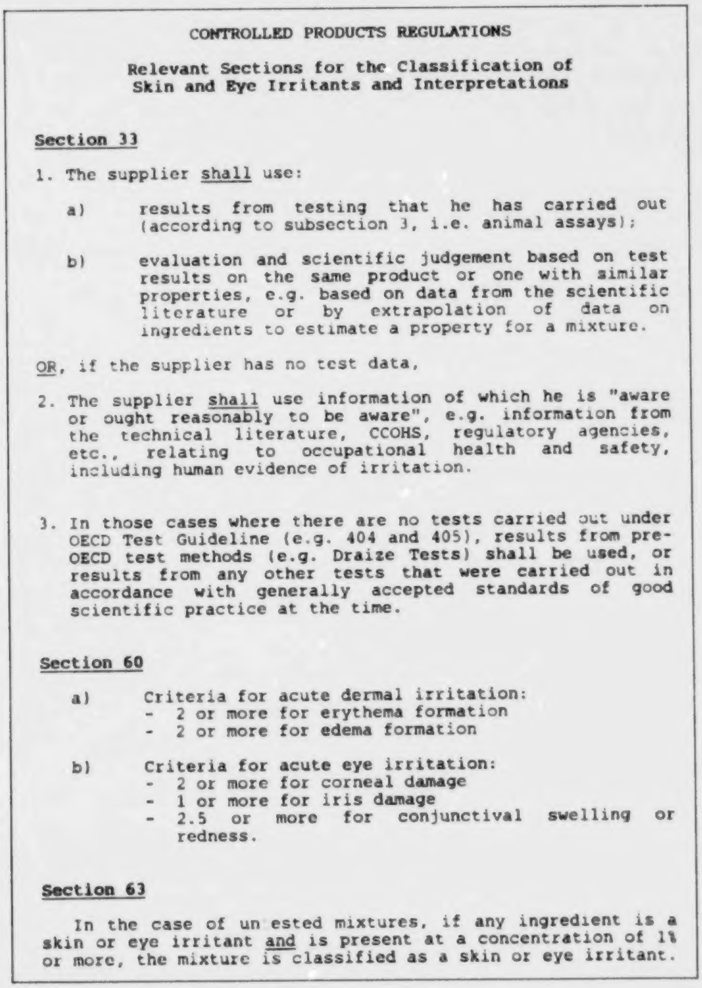
And finally, in Subsection 3, there is an indication of what I have already talked about—you shall use OECD test guidelines, or "in the case of skin or eye irritation, the Draize Test" or any other test, and so on. So I have dragged Subsection 3 up into Subsection 1 to allow you to understand what it is referring to, because Subsections 1 and 3 in Section 33 of the Regulations are tied together.

Richard Morris *continued*

The second section that I've dealt with in the excerpt from the Controlled Products Regulations is Section 60. We won't go into the actual numbers in the criteria for skin and eye irritation, but the basic point is that the OECD test guideline is an animal assay. There's a grading system based on certain pathological findings of inflammation.

Finally, Section 63 deals with what you do in the case of mixtures involving skin irritants. Obviously you can't apply a formula, so that discussion isn't relevant here. You could test the mixture or use the 1% cutoff.

Slide 29



CONTROLLED PRODUCTS REGULATIONS

**Relevant Sections for the Classification of
Skin and Eye Irritants and Interpretations**

Section 33

1. The supplier shall use:
   - a) results from testing that he has carried out (according to subsection 3, i.e. animal assays);
   - b) evaluation and scientific judgement based on test results on the same product or one with similar properties, e.g. based on data from the scientific literature or by extrapolation of data on ingredients to estimate a property for a mixture.

OR, if the supplier has no test data,

2. The supplier shall use information of which he is "aware or ought reasonably to be aware", e.g. information from the technical literature, CCOHS, regulatory agencies, etc., relating to occupational health and safety, including human evidence of irritation.

3. In those cases where there are no tests carried out under OECD Test Guideline (e.g. 404 and 405), results from pre-OECD test methods (e.g. Draize Tests) shall be used, or results from any other tests that were carried out in accordance with generally accepted standards of good scientific practice at the time.

Section 60

a) Criteria for acute dermal irritation:
   - 2 or more for erythema formation
   - 2 or more for edema formation

b) Criteria for acute eye irritation:
   - 2 or more for corneal damage
   - 1 or more for iris damage
   - 2.5 or more for conjunctival swelling or redness.

Section 63

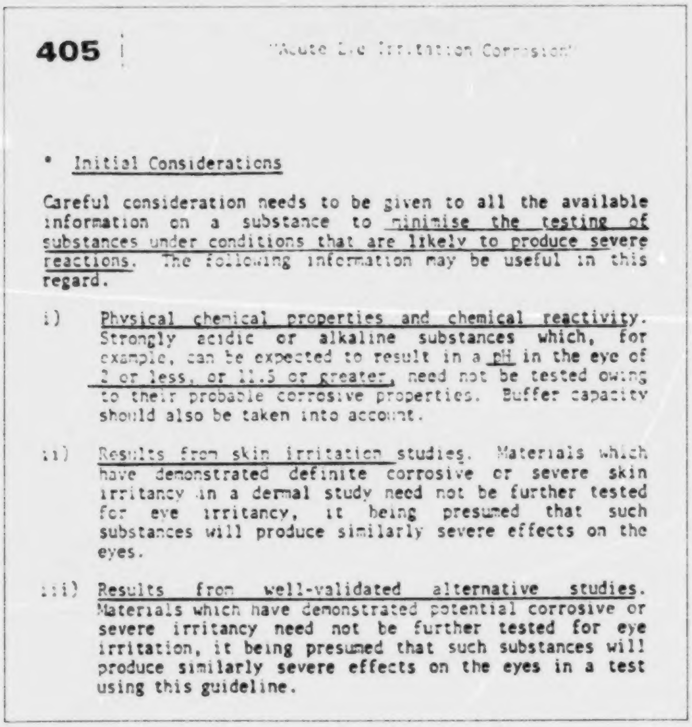
In the case of untested mixtures, if any ingredient is a skin or eye irritant and is present at a concentration of 1% or more, the mixture is classified as a skin or eye irritant.

Richard Morris *continued*

This is my interpretation, based on discussions with Consumer and Corporate Affairs and their draft interpretations. When they come out, I suspect that they will make very good reading.

I also want to deal with the wide variety of testing methods available for skin and eye irritation. As you get into the methodology you discover that there are significant differences in the ways that various tasks are carried out. These could have a significant impact on the classification process. So, the third question I would like to raise is what are some of these differences in the methodology and basically what is their potential impact on classification?

Slide 30



405 "Acute Eye Irritation/Corrosion"

- Initial Considerations

Careful consideration needs to be given to all the available information on a substance to minimise the testing of substances under conditions that are likely to produce severe reactions. The following information may be useful in this regard.

i) Physical chemical properties and chemical reactivity. Strongly acidic or alkaline substances which, for example, can be expected to result in a pH in the eye of 2 or less, or 11.5 or greater, need not be tested owing to their probable corrosive properties. Buffer capacity should also be taken into account.

ii) Results from skin irritation studies. Materials which have demonstrated definite corrosive or severe skin irritancy in a dermal study need not be further tested for eye irritancy, it being presumed that such substances will produce similarly severe effects on the eyes.

iii) Results from well-validated alternative studies. Materials which have demonstrated potential corrosive or severe irritancy need not be further tested for eye irritation, it being presumed that such substances will produce similarly severe effects on the eyes in a test using this guideline.

I would like to start by looking at the OECD Test Guideline 405 which attempts to deal with the problem of corrosion and irritation. When you start to test and evaluate a material for irritation and corrosion, you have to determine whether your material is chemically reactive. You also have to find a way of differentiating between that chemical reactivity and a true toxic effect. From the point of view of human experience, corrosives and irritants seem very similar. The human experience is stinging and a sensation of pain. That's not what the criteria state. The criteria say erythema

Richard Morris *continued*

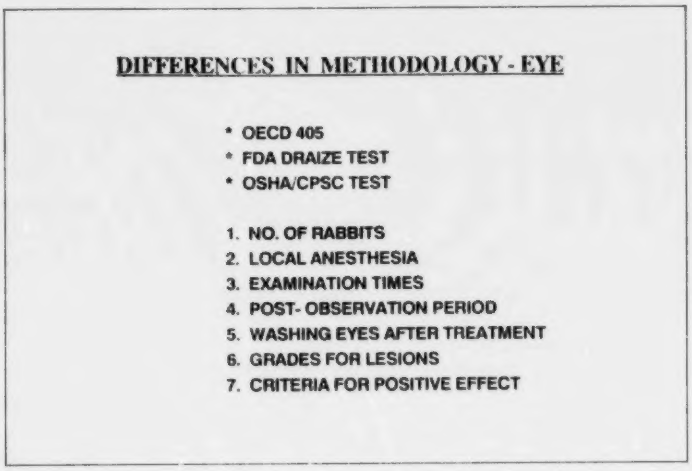
(redness) and inflammation. It is true that workers who are exposed to known severe irritants have both inflammation and redness, and the edema. But people mostly think of irritation in terms of pain associated with the exposure, especially in the mucous membrane.

The OECD test guideline says that you should look at the chemistry of the product before you test it to determine whether or not it is corrosive on chemical grounds alone. You may already know through pH or some other chemical manifestation that it is corrosive, and therefore, it is not treated as an irritant when testing.

Secondly, it is suggested that you use skin irritation studies rather than go directly into an eye irritation study. That makes basic common sense. It may not be necessary to use live tissue. Start with less sensitive tissue to determine whether or not the chemical is really reactive. If it reacts with the tissue, call it a corrosive, don't call it an irritant/corrosive. That is not what we are looking for in WHMIS. We want to communicate the hazards, but we want to communicate the hazards that workers should be protecting themselves against. If it is chemical hazard, then you want to prevent actual skin or eye contact.

Thirdly, the animals or workers are guinea pigs. When you use a new product, mistakes are made. People get it on their hands, or get it in the creases of their clothing, and as they sweat they develop acute inflammation. These are the sources of information that tell you that you don't have to go any further. You already know that under certain conditions the material can act as an irritant or as a corrosive. There are ways to judge both by carrying out tests and by looking at a material to make some logical and reasoned decisions as to whether or not it is a corrosive or an irritant. Most of us who work with chemicals that fall into these groups are aware that some chemicals at full strength may be very corrosive and the irritation is a very small part of the whole thing, from the point of view of toxicity. But as you dilute it beyond the point at which it is corrosive, the potential toxicity can be manifested. So there are materials that could be both corrosive and non-corrosive depending on the level of exposure and the concentration. For the most part, materials should be one or the other. I would certainly not like to see stylized "T"s on all corrosive substances.

Slide 31



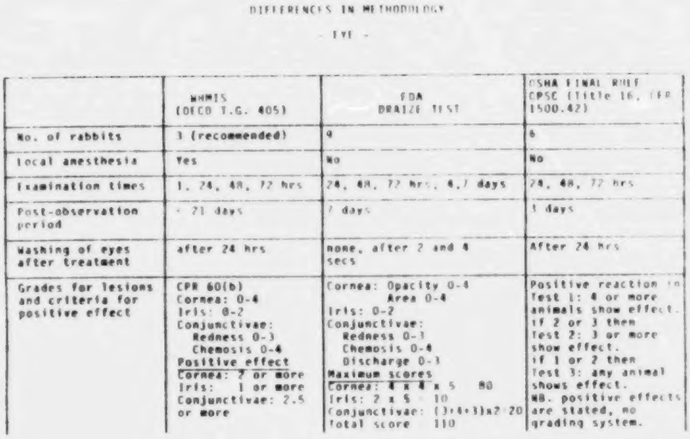
DIFFERENCES IN METHODOLOGY - EYE

- OECD 405
- FDA DRAIZE TEST
- OSHA/CPSC TEST

1. NO. OF RABBITS
2. LOCAL ANESTHESIA
3. EXAMINATION TIMES
4. POST- OBSERVATION PERIOD
5. WASHING EYES AFTER TREATMENT
6. GRADES FOR LESIONS
7. CRITERIA FOR POSITIVE EFFECT

Three basic kinds of tests for the eye have been used to determine the irritation. All of them are derived from the methodology used by Draize which was developed during the second World War. They go back a long way and there has been much fine tuning and alterations to the original tests.

Slide 32



DIFFERENCES IN METHODOLOGY

- EYE -

	WHMIS (OECD T.G. 405)	FDA DRAIZE TEST	OSHA FINAL RULE CPSC (Title 16, CFR 1500.42)
No. of rabbits	3 (recommended)	9	6
Local anesthesia	Yes	No	No
Examination times	1, 24, 48, 72 hrs	24, 48, 72 hrs, 4,7 days	24, 48, 72 hrs
Post-observation period	< 21 days	7 days	3 days
Washing of eyes after treatment	after 24 hrs	none, after 2 and 4 secs	After 24 hrs
Grades for lesions and criteria for positive effect	CPR 60(b) Cornea: 0-4 Iris: 0-2 Conjunctivae: Redness 0-3 Chemosis 0-4 Positive effect Cornea: 2 or more Iris: 1 or more Conjunctivae: 2.5 or more	Cornea: Opacity 0-4 Area 0-4 Iris: 0-2 Conjunctivae: Redness 0-3 Chemosis 0-4 Discharge 0-3 Maximum scores Cornea: 4 x 4 x 5 = 80 Iris: 2 x 5 = 10 Conjunctivae: (3+4+3)x2=20 Total score = 110	Positive reaction in Test 1: 4 or more animals show effect. if 2 or 3 then Test 2: 3 or more show effect. if 1 or 2 then Test 3: any animal shows effect. NB. positive effects are stated, no grading system.

There is the OECD Test Guideline 405; another is the FDA Draize test, which is different; and the OSHA and the Consumer Products Safety Commission test which is in the Code of Federal Regulations (CFR) 1500.42.

There are differences in the number of rabbits that are recommended in the various tests. Because of animal rights

Richard Morris *continued*

concerns there has been a movement to use fewer and fewer animals as surrogates for the testing procedure. The actual number of subjects used probably doesn't have a major effect in classification. Local anesthesia has also been added in more recent protocols to avoid the problem of animal suffering.

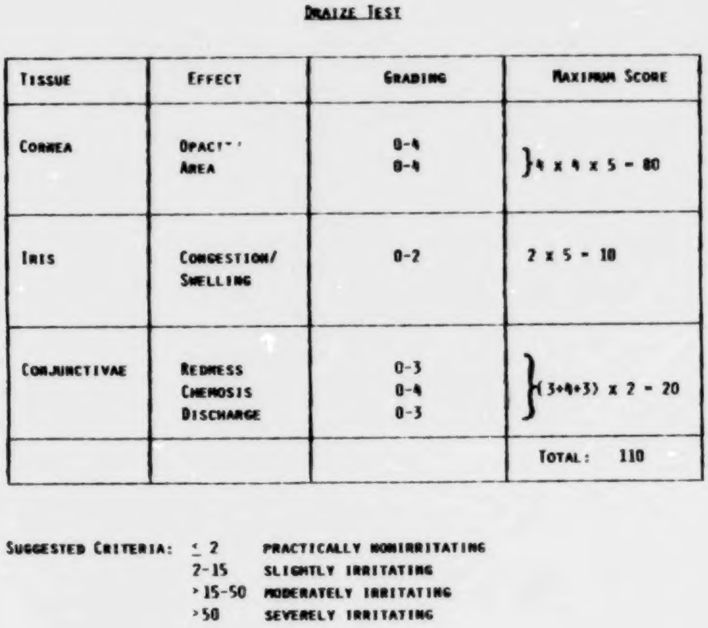
Examination times could be significant. In WHMIS, using the OECD Test Guideline, the eyes are examined as early as one hour after exposure. This would show early indications and from an OECD standpoint, would allow you to terminate an experiment if you already have answers. This is in case of a material that has a particularly severe effect for the eyes. One wouldn't expect that this would have a major impact in classification.

The post-observation period differs considerably. This would have an effect on the determination of the reversibility of the inflammation. If you have correctly identified the corrosive agents, this may not have any real impact.

The washing of eyes after treatment varies considerably, especially in the FDA test, where it's either not done at all, or done after 2 or 4 seconds, which allows for a very short exposure and is particularly useful for assessing more chemically reactive materials. If you are actually using the data from tests with 2 and 4 seconds exposure, that will have a major impact on the classification. You could underclassify materials as eye irritants because the test material has been washed out rather quickly.

Finally, grades for lesions and criteria for positive effect differ considerably in the different test systems. This area will probably have the greatest impact in classification. It will force re-classification of materials that were previously classified using different (non-WHMIS) criteria. The WHMIS criteria are very straightforward, but how often are the data going to be available to make the judgment? In the FDA Draize test, there are significant differences in some of the actual end points. It also has a very complex scoring system.

Slide 33



Draize Test

Tissue	Effect	Grading	Maximum Score
Cornea	Opacity Area	0-4 0-4	} 4 x 4 x 5 = 80
Iris	Congestion/ Swelling	0-2	2 x 5 = 10
Conjunctivae	Redness Chemosis Discharge	0-3 0-4 0-3	} (3+4+3) x 2 = 20
			Total: 110

Suggested Criteria:		
	≤ 2	Practically nonirritating
	2-15	Slightly irritating
	>15-50	Moderately irritating
	>50	Severely irritating

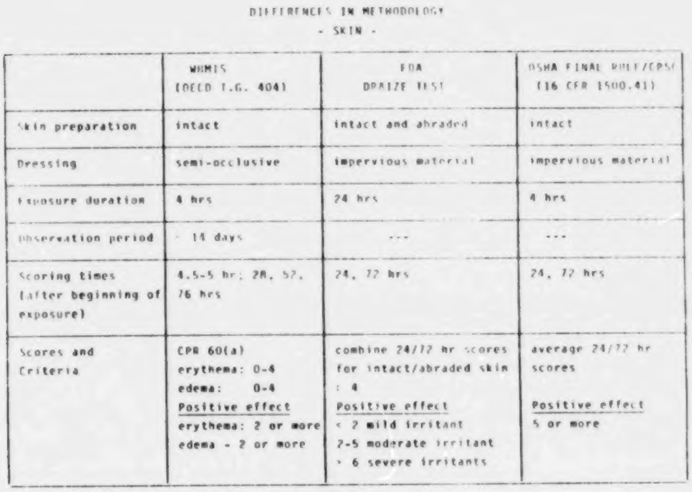
This presents a review of the FDA Draize scoring system. You can see the cornea is heavily weighted and the scores are multiplied by one another to develop 80 of the 110 final score. The iris is weighted by 5 and the conjunctivae scores are added and multiplied by 2. Realistically, from the toxicological standpoint, the conjunctivae are the mucous membranes that would be exposed first, then after penetration, the iris and then finally the cornea. By the time something has penetrated to damage the cornea, you can see why it is so heavily weighted. The suggested criteria are based on discussions I've had with representatives of industry who are attempting to use the 110-point scales and to apply them to WHMIS. I haven't put the actual WHMIS equivalents there, but you can see the scores are between 15 and 50 and this is where you have to use judgment. It is a question of where you draw the line. Only you can know where you want to draw that line by going back to the data if you have access to it, or just choosing a point and using it across the board.

Finally, looking at the OSHA grading system (Slide 33) you can see that it is quite different again. There is a very complex system of testing and re-testing depending on whether the results are positive. There is not an actual grading system in their final rule and it is done in a very descriptive way. It would be difficult to translate something that has been tested under Title 16, CFR 1500.42 into a WHMIS-type of criterion.

Richard Morris *continued*

When it comes to the question of justifying, it comes down to a policy. You make a policy statement—this is how I am going to do it—and you document it and use it for your products. You don't have to come up with de novo justifications for each product; you use a decision you made within your company on how to deal with certain types of products and certain types of effects.

Slide 34

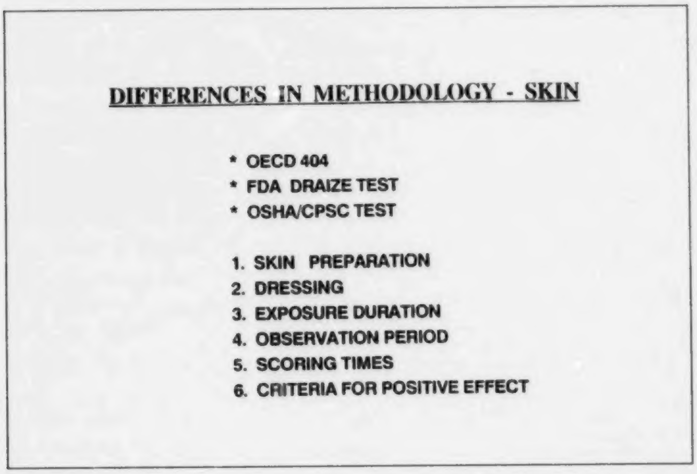


DIFFERENCES IN METHODOLOGY
- SKIN -

	WHMIS (OECD T.G. 404)	FDA DRAIZE TEST	OSHA FINAL RULE/CPSC (16 CFR 1500.41)
Skin preparation	intact	intact and abraded	intact
Dressing	semi-occlusive	impervious material	impervious material
Exposure duration	4 hrs	24 hrs	4 hrs
Observation period	≤ 14 days	---	---
Scoring times (after beginning of exposure)	4.5-5 hr; 28, 52, 76 hrs	24, 72 hrs	24, 72 hrs
Scores and Criteria	CPR 60(a) erythema: 0-4 edema: 0-4 Positive effect erythema: 2 or more edema - 2 or more	combine 24/72 hr scores for intact/abraded skin : 4 Positive effect < 2 mild irritant 2-5 moderate irritant > 6 severe irritants	average 24/72 hr scores Positive effect 5 or more

As in the case of the eye tests, there are three different protocols for skin tests. This outlines the major differences in methodology.

Slide 35



DIFFERENCES IN METHODOLOGY - SKIN

- * OECD 404
- * FDA DRAIZE TEST
- * OSHA/CPSC TEST

1. SKIN PREPARATION
2. DRESSING
3. EXPOSURE DURATION
4. OBSERVATION PERIOD
5. SCORING TIMES
6. CRITERIA FOR POSITIVE EFFECT

Richard Morris *continued*

There are some significant differences in the methodology of skin that could affect the classification process. For skin preparation, the FDA test uses both the intact and abraded skin. If you use an abraded skin, you are going to get a greater incidence of irritation effects. In the case of dressing, if you use an impervious material rather than a semi-occlusive one, you are going to aggravate the irritation and therefore, bring it on sooner and with more severe symptoms. OSHA does use the intact skin, but it also uses the impervious material.

The exposure duration is significantly different between the WHMIS and OSHA approaches and the FDA approach, under which many materials have been tested. The difference between 4 hours' and 24 hours' exposure is very significant. It means that if you have a lot of materials that have been tested for 24-hour exposure, there may be a lot of over-classification and you have to use some judgment.

The observation period deals with the question of reversibility. The OECD does allow for that; the other systems don't mention it.

Scoring times vary between systems and the major difference is that OECD Test Guidelines use earlier scoring times for the same reason as we saw in the methodology for eyes. It is also timed after the beginning of the exposure rather than from the end of the exposure, as the other two systems are. There is a slight difference in the numbers, which I don't think is crucial.

The scores and criteria differ between the different methodologies. If you look at the Controlled Products Regulations in terms of the criteria, the positive effects are very clearly stated. In the FDA approach, the 24-hour and 72-hour scores are combined for the intact and the abraded skin and then divided by 4, so the numbering scheme of 2-5 for moderate irritation based on that approach can't be directly related to the WHMIS score of 2. Because of the abraded skin and the 24-hour exposure, the number would have to be something more than 2, and you will have to use some professional judgment either on a case-by-case basis or by developing a policy and choosing a number and sticking to it. In the case of the OSHA Final Rule, the positive effect is 5 or more and it reflects their use of an impervious dressing. If you add up the WHMIS scores, that would be 4 or more, and I think that is a reasonable increase based on the differences in methodology.

There are differences in methodology that will affect the classification process, so you have to be aware of the method used. You can't just assume that if you have a score or a descriptive result you can immediately apply WHMIS criteria. It is going to involve a necessary step—evaluation and scientific judgment.

Slide 36

DATA AVAILABILITY

ANIMAL DATA

1. SUPPLIER'S OWN RESULTS
   - OECD
   - PRE-OECD
2. PUBLISHED RESULTS
   - PRIMARY SOURCE (HARD DATA)
   - SECONDARY SOURCE (SOFT DATA)

HUMAN EVIDENCE

Data availability is the last question I want to deal with. What about its effect on the classification process? According to the regulations, the supplier should use his/her own results or results from an "upstream" supplier using OECD or pre-OECD type tests or published results. Realistically, in the case of skin and eye irritation, it is not one of those toxic end points that has a wealth of information in the literature. It is probably more likely to be found in technical information and other kinds of in-house reports, but you are not going to find a lot about it in scientific literature, unlike carcinogenicity or some other toxic effects.

I've broken down the published results into two sources: primary sources, which are scientific papers—hard data or raw data; or secondary sources. By far, the majority of people will be looking at secondary sources.

Slide 37

Ethylenimine

Physiological Response

Acute Toxicity. Ethylenimine is highly to extremely toxic by all routes of exposure to animals; especially if exposures are repeated (Tables 38.1 and 38.2). The effects in experimental animals have been studied by several groups of investigators (8, 13-15). The high toxicity and the unique effect of ethylenimine on the kidney were recognized as early as 1898 by Paul Ehrlich. The free imine is a potent skin irritant and vesicant. Lesions of the skin are slow to heal. Silver and McGrath (14) exposed mice to measured concentrations of ethylenimine in air for 10 min and found the LC_{50} = 2236 ppm. The animals exhibited signs of irritation of the eyes and nose during exposure. Deaths were delayed, occurring from about 24 hr after exposure throughout the 10-day observation period. Carpenter et al. (15) exposed rats and guinea pigs to concentrations of ethylenimine for varying periods of time (see Table 38.2). They also found that deaths were delayed. The animals exhibited extreme respiratory difficulty after exposures to concentrations above 10 ppm and there was evidence of irritation of the eyes and nose at 100 ppm. Repeated 7-hr exposures for several months to 1.65 ppm caused essentially no effects. However, similar exposure to 3.5 ppm caused illness and death in several species (8).

It was determined experimentally that eye and nose irritation in humans becomes evident at about 100 ppm (15).

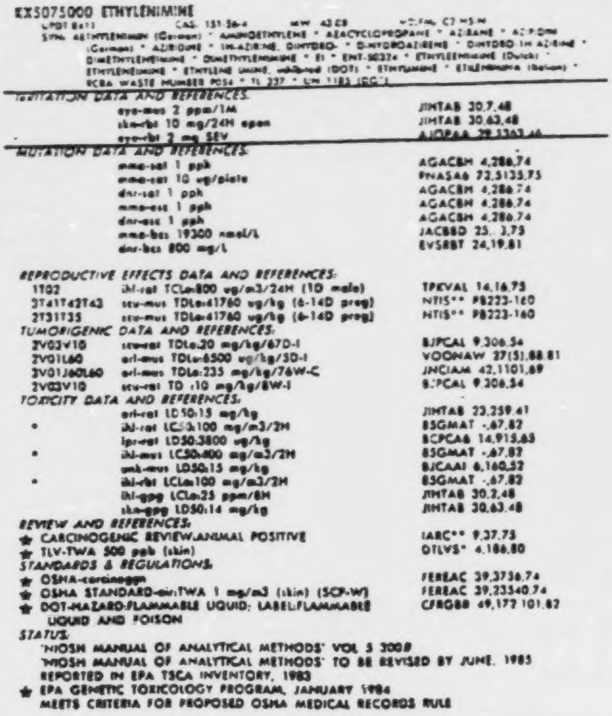
ETHYLENIMINE

CAS RN: 151564 NIOSH #: KX 5075000
mf: C_2H_5N; mw: 43.08

TOXICITY DATA: 3	CODEN:
eye-mus 2 ppm/1M	JIHTAB 30,7,48
skn-rbt 10 mg/24H	JIHTAB 30,63,48
eye-rbt 2 mg SEV	AJOPAA 29,1363,46
mmo-omi 600 ppm/2H-C	DBANAD 31,1477,78
mmo-omi 500 mg/L	AMBBBR 6,15,74
dlt-oin-par 20 mmol/L	M'JREAV 15,67,72
dni-hmn:hla 500 umol/L	C 'REA8 38,4445,78
cyt-hmn:lym 1 umol/L/1H	A..TODN 46,61,80
cyt-rat-ihl 8 ug/L/17W	TPKVAL 13,51,73
dni-mus-ivg 1 pph	JIDEAE 62,378,74
scu-mus TDLo:41760 ug/kg (6-14D preg)	NTIS** PB223-160
scu-rat TDLo:20 mg/kg/67D-I:NEO	BJPCAL 9,306,54
orl-mus TDLo:235 mg/kg/76W-C:CAR	JNCIAM 42,1101,69
scu-rat TD:10 mg/kg/8W-I:ETA	BJPCAL 9,306,54
orl-rat LD50:15 mg/kg	JIHTAB 23,259,41
ihl-rat LCLo:25 ppm/8H	JIHTAB 30,2,48
ipr-rat LD50:3800 ug/kg	BCPCA6 14,915,65
ihl-mus LCLo:1800 mg/m3/10M	NDRC** NDCrc-132,Aug,42
unk-mus LD50:15 mg/kg	BJCAAI 6,160,52
ihl-gpg LCLo:25 ppm/8H	JIHTAB 30,2,48
skn-gpg LD50:14 mg/kg	JIHTAB 30,63,48

Carcinogenic Determination: Animal Positive IARC** 9,37,75.

THR: HIGH irr of skn, eyes, mu mem and via oral, dermal, ipr and inhal routes.



KX5075000 ETHYLENIMINE
UPDT 8411 CAS: 151-56-4 MW: 43.08 MOLFM: C2-H5-N
SYN: AETHYLENIMIN (German) * AMINOETHYLENE * AZACYCLOPROPANE * AZIRANE * AZIRIDIN (German) * AZIRIDINE * 1H-AZIRINE, DIHYDRO- * DIHYDROAZIRENE * DIHYDRO-1H-AZIRINE * DIMETHYLENEIMINE * DIMETHYLENIMINE * EI * ENT-50324 * ETHYLEENIMINE (Dutch) * ETHYLENEIMINE * ETHYLENE IMINE, inhibited (DOT) * ETHYLIMINE * ETILENIMINA (Italian) * RCRA WASTE NUMBER P054 * TL 337 * UN 1185 (DOT)

IRRITATION DATA AND REFERENCES:

	eye-mus 2 ppm/1M	JIHTAB 30,7,48
	skn-rbt 10 mg/24H open	JIHTAB 30,63,48
	eye-rbt 2 mg SEV	AJOPAA 29,1363,46

MUTATION DATA AND REFERENCES:

	mmo-sat 1 pph	AGACBH 4,280,74
	mmo-sat 10 ug/plate	PNASA6 72,5135,75
	dnr-sat 1 pph	AGACBH 4,280,74
	mmo-esc 1 pph	AGACBH 4,280,74
	dnr-esc 1 pph	AGACBH 4,280,74
	mmo-bcs 19300 nmol/L	JACBBD 25,3,75
	dnr-bcs 800 mg/L	EVSRBT 24,19,81

REPRODUCTIVE EFFECTS DATA AND REFERENCES:

1T02	ihl-rat TCLo:800 ug/m3/24H (10 male)	TPKVAL 14,16,73
3T41T42T43	scu-mus TDLo:41760 ug/kg (6-14D preg)	NTIS** PB223-160
2T31T35	scu-mus TDLo:41760 ug/kg (6-14D preg)	NTIS** PB223-160

TUMORIGENIC DATA AND REFERENCES:

2V02V10	scu-rat TDLo:20 mg/kg/67D-I	BJPCAL 9,306,54
2V01L60	orl-mus TDLo:6500 ug/kg/5D-I	VOONAW 27(5),88,81
3V01J60L60	orl-mus TDLo:235 mg/kg/76W-C	JNCIAM 42,1101,69
2V02V10	scu-rat TD :10 mg/kg/8W-I	BJPCAL 9,306,54

TOXICITY DATA AND REFERENCES:

	orl-rat LD50:15 mg/kg	JIHTAB 23,259,41
•	ihl-rat LC50:100 mg/m3/2H	85GMAT -,67,82
	ipr-rat LD50:3800 ug/kg	BCPCA6 14,915,65
•	ihl-mus LC50:400 mg/m3/2H	85GMAT -,67,82
	unk-mus LD50:15 mg/kg	BJCAAI 6,160,52
•	ihl-rbt LCLo:100 mg/m3/2H	85GMAT -,67,82
	ihl-gpg LCLo:25 ppm/8H	JIHTAB 30,2,48
	skn-gpg LD50:14 mg/kg	JIHTAB 30,63,48

REVIEW AND REFERENCES:

★ CARCINOGENIC REVIEW:ANIMAL POSITIVE	IARC** 9,37,75
★ TLV-TWA 500 ppb (skin)	DTLVS* 4,186,80

STANDARDS & REGULATIONS:

★ OSHA-carcinogen	FEREAC 39,3756,74
★ OSHA STANDARD-air:TWA 1 mg/m3 (skin) (SCP-W)	FEREAC 39,23540,74
★ DOT-HAZARD-FLAMMABLE LIQUID; LABEL:FLAMMABLE LIQUID AND POISON	CFRGBR 49,172,101,82

STATUS:
'NIOSH MANUAL OF ANALYTICAL METHODS' VOL 3 300#
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REPORTED IN EPA TSCA INVENTORY, 1983
★ EPA GENETIC TOXICOLOGY PROGRAM, JANUARY 1984
MEETS CRITERIA FOR PROPOSED OSHA MEDICAL RECORDS RULE

Richard Morris *continued*

I've taken excerpts from three different well-known secondary sources for the chemical Ethylenimine, as an example. I have underlined portions of the text that indicate the things that you will see in secondary literature—what I would call soft data. The first example is from Patty, a description of studies that have taken place; there are statements like "The free imine is a potent skin irritant and vesicant." How can you use WHMIS criteria for that? You can't, not easily; it takes some judgment. You could go to the original paper since the reference is given. At the end of the paragraph, it does say something about eye and nose irritation in humans at about 100 ppm and again a reference is given that might be helpful in making a decision as to whether you want to classify this as a skin and eye irritant.

The bottom left excerpt is from Sax. At the very bottom you will see the phrase, based on his interpretation, "High irritation of skin, eyes, mucous membranes..." and so on. Again, this is a subjective judgment, so how do you apply the WHMIS criteria?

On the bottom right is an excerpt from RTECS; the references are given in their acronymic form, but the actual data they present do not give score numbers—it says so many milligrams in the eye. You could use judgment on that or you could go back to the primary source and see if the study enables you to make sense of what the scoring would have been, based on the OECD Test Guidelines, because the guideline does give you the basis for the scoring.

There are ways to apply judgment; there are logical approaches which can be used to achieve it to classify materials under WHMIS.

In summary, a couple of different effects could be misinterpreted that could have an effect on the classification—corrosion and irritation. It is important to determine which it is that your product is likely to exhibit. If you decide it is mostly a corrosive agent given its physical and chemical properties, then it is important to state that as the alert on the label. It doesn't mean that in a risk statement you wouldn't indicate that under certain conditions it may be found to be irritating, but you wouldn't necessarily have to classify it as an irritant. We don't want double classifications; we aren't trying to proliferate the number of pictograms on the label.

Questions

Geoff Granville

Richard, one of the interesting things was your comment about the OECD skin study which takes the first evaluation between 1/2 and 1 hour after the study has finished. Some of the companies

Geoff Granville *continued*

I am talking to are looking at skin irritation and finding materials being over-classified because just 1 hour after exposure, a lot of materials end up looking very irritating. You have had the material under dressing so the skin has been immobilized for a 4-hour period of time. It is quite easy to hit a score of 4 or more for redness given such a situation. That irritation has been known to disappear very rapidly thereafter. So you are not dealing with an irritant, you are dealing with something that on a very short term basis has caused redness. We are wondering whether in time you can actually make a submission to government to say that 1-hour score should be turned to a judgmental score. The reason OECD developed it in the first place was to be humane and not leave corrosives on the skin for a 24-hour period before you scored.

Richard Morris

It is a problem. Once you take the dressing off, even if you don't wash the skin, the effect could very well dissipate. This is probably part of the fine tuning that may have to go on in terms of our interpretation of the regulations. The kind of irritation that we are looking for is the kind that is sustained long enough to cause significant discomfort to the person. We are not addressing very minor effects. This could have a tremendous impact on the classification process. Many substances, including food items, left on the skin that long would cause irritation; and we are certainly not recommending that food and other consumer products have WHMIS labels on them. We are looking for legitimate skin irritants; ones that have a sustained effect. The mechanism to deal with this problem may have to be through interpretation.

Don Macaulay

In our process of classification, we have come across a number of supplier MSDSs, particularly in the US, that will state that the material is irritating. Based on that, how strictly are these guidelines being applied either in Canada or the US at the moment?

Richard Morris

Both Canada and the US are signatories to OECD, but it has been my understanding that the Americans have chosen to ignore the OECD Test Guidelines in their own legislation. They have their own test guidelines and some of them are very similar to the OECD Test Guidelines. But there are some significant differences. We don't do a lot of toxic testing in Canada, and the labs that do are aware of the OECD Test Guidelines. I would think they wouldn't be very far off those results. If you were testing, you tell the particular lab you are using that you want the materials tested

Richard Morris *continued*

according to the OECD Test Guidelines and you would be told whether the lab was prepared to do so. I would suspect it would; it would have in-house protocols that have been developed over the years.

Don Macaulay

I am trying to establish that when we see the word "irritant" on a Material Safety Data Sheet for a raw material that we may be using in our blends, we can take that at its face value. In our experience so far, the word seems to be used quite loosely; it doesn't follow any strict definition, which seems to be what this regulation is trying to state.

Richard Morris

I would like to see a move away from using the word "irritant" when the material is clearly a corrosive agent. It is obvious from human experience that corrosive agents cause irritation; from a physiological standpoint, the material is simply "burning through" and causing an effect on the nerve endings and giving them a message. Is that irritation? No, that's corrosion. We have to understand the difference. We are talking about a toxic effect versus a chemical effect. If you have any evidence to support that it's a chemical effect, call it a corrosive agent.

John Purdy
Ciba-Geigy Canada Limited

You described a hierarchy of testing from corrosivity down to sensitization. Can that kind of thinking be extended to respiratory sensitization to avoid the need to research that separately?

Richard Morris

I talked about skin and eye irritants in terms of corrosion, irritation and sensitization, but you could apply the same thing to respiratory corrosion, irritation and sensitization. If you look at the criteria, we have sensitization, we don't have irritation per se, but it would react very much like a mucous membrane. We don't have corrosion explicitly either, because if something were going to corrode the respiratory system, it should have been stopped before it got into the air. But it may not be a skin corrosive, so one would have to determine that from the chemical physical properties. You would have to know that the material, if it got into the air, is capable of reacting with a sensitive tissue like the lung or mucous membranes. You would have to know that from the chemical findings. As a Health and Welfare representative or as a

Richard Morris *continued*

toxicologist, I wouldn't advocate that the first step in determining corrosives involve tests on rabbit eyes or other live tissue. It's certainly not always necessary and it would certainly not be recommended when there are alternative approaches to assessing corrosivity.

John Purdy

I was particularly concerned about those things which are not corrosive, but which may show sensitization. Are there any generalizations that could be made to avoid respiratory sensitization tests after something is known not to be particularly irritating in other ways? Should you examine respiratory sensitization if you've already excluded a material from classification on the grounds of skin sensitization?

Richard Morris

There is not a lot of good correlation between skin and lung sensitizers. Logically, you might expect it but a relatively weak skin sensitizer could be a strong respiratory sensitizer. So it not good judgment to make assumptions by looking at skin sensitizers. You have to hope to find the information through human exposure because humans are exposed to chemicals all the time and it is an individual type of response. I don't think we are going to be testing thousands of chemicals using guinea pigs. That's not practical; it is not even a practical screening method. There are no practical screening methods for sensitizers. As you build up cases from your work force, you will know that a chemical obviously seems to cause some sort of sensitization and put some precautions in place. Someone asked during the coffee break "What if I know there is a class of substances out of which a few are known to be sensitizers. Are you going to say in the face of no data that all of the substances are sensitizers?" No, I would say that would be a bad thing to do. You may very well find it useful to indicate on a MSDS that there are some related substances that are sensitizers and indicate which ones they are, pointing out that they don't happen to be the one that is in your product. Nevertheless, it's information.

Lucille Green
Inco Limited

Is it intended that the effects of mechanical irritation from a particulate material be included in your definition of irritation?

Richard Morris

There are both physical and chemical irritants. I think of this toxic effect as being a chemical in nature. Primary irritation is normally thought of as chemical irritation. It is true that there are mechanical type irritants and quite often they tend to be the chronic ones. WHMIS deals with acute skin irritation, it's not chronic, and you would have to deal with it in that way.

Lucille Green

Would a material that might form dusts that could be inhaled be considered irritating to the respiratory tract?

Richard Morris

Yes, but it is not included in skin and eye irritation. You would have to pick that up under some other criteria.

Classification of Material 1

Presenter: Robert Whiting

Lillian Vine

When we were planning this workshop, we thought the best way to exchange information about classifying was to actually classify. So you are going to have actual classifications of two hypothetical mixtures invented for this purpose.

Doing the first classification is Bob Whiting of the Canadian Centre for Occupational Health and Safety, where he is manager of the Material Hazards section of Technical Services. Bob has been very involved in the Ingredient Disclosure List of WHMIS.

Bob did his undergraduate and graduate work at the University of Toronto, with his PhD in the Department of Medical Biophysics. His PhD thesis was the Studies of Nucleic Acid Sequences by Dark Field Electron Microscopy. He received the Medical Research Council's Studentship and National Cancer Institute of Canada Studentship. He was a Post-doctoral Fellow of the National Cancer Institute of Canada in the Cancer Research Centre of the University of British Columbia from October 1975 to June 1978; a research associate in the Environmental Carcinogenesis Unit, BC Cancer Research Centre from July 1978 to September 1980, at which time he came to the Centre as a Project Scientist.

The panelists will react to Bob's classification as they later will to Marc Baril's. Your questions should be reserved until you hear the second classification session, which David Gaylor will chair.

Robert Whiting

Material 1 was very ingeniously designed to bring out many of the practical aspects of classification—judgment, evaluation and collection of information. I must admit that in the process of working through the classifications of these three ingredients in detail in preparation for the workshop, I changed my views on some of the classifications. In fact, since the last workshop, I've changed my view on at least one of the points in the classification of one of these materials. Doing a classification is not a cut-and-dried process.

On the other hand, I think it's fair to say that, given the information available on these three materials, the overall classification of the product would not have been greatly affected by what I changed my mind on, or by any differences of opinions likely to arise among the panelists.

Slide 38

Material 1

	Maleic Anhydride 5%	Chloroform 20%	MEK 75%
A. Compressed Gas	—	—	—
B. Flammable & Combustible	—	—	Flammable Liquid
C. Oxidizing Material	—	—	—
D. Poisonous & Infectious			
1. Immediate	Toxic	Very Toxic	—
2. Other	Very Toxic	Very Toxic	Toxic
E. Corrosive Material	Corrosive	—	—
F. Dangerously Reactive	—	—	

This slide shows the composition of Material 1. It is composed of maleic anhydride, chloroform, and methyl ethyl ketone in concentrations of 5%, 20% and 75%. A summary of the overall classification of the individual ingredients is shown, highlighting the areas in which we really have to concentrate our effort in doing a classification—flammable liquid and various toxic categories. For purposes of this workshop, it is important that we go through every point of the classification of every material; in some cases, we have to use judgment or our experience, for example, to say that maleic anhydride is not a compressed gas, or that chloroform is not a dangerously reactive material. But we must look carefully at both the criteria and the data and avoid quick judgments.

I would like to begin with maleic anhydride and discuss the classification exercise I went through. The panelists will comment on the same classification which they have each worked on independently.

Slide 39

Maleic Anhydride

	Property	Meets Criteria?
A. Compressed Gas	Vapour Pressure 0.00005 mm Hg	No
B. Flammable & Combustible	Flash Point 102° C	No
C. Oxidizing Material	Not Oxygen Donor	No
E. Corrosive Material	Corr. Animal Skin TDG Class 8	Yes
F. Dangerously Reactive Material	Not Violently Self-Reactive. Reaction With Water Gives Maleic Acid. But Violent Decomposition When Heated with 0.1% NaOH	No?

Here I have covered all the classes except Class D, which deserves the greatest amount of attention.

Beginning with Compressed Gas, it seems clear that, given a vapour pressure of 0.0005 mm mercury, it is not a compressed gas. It is very rare that a material which is a liquid or a solid at room temperature would meet criteria for compressed gas, although some may if they happen to be extremely volatile.

For Flammable and Combustible Material, Class B, the flash point is 102°C. The cutoff for flash point is 93°C and it is not regarded as a flammable/combustible material. Maleic anhydride is not an oxygen donor and is not known to take part in any oxidation reactions—it is not an oxidizing material. In fact, none of the three materials in this product are oxidizing materials.

Class E, Corrosive Material, brings us to our first difficulty. Maleic anhydride is classified under TDG Regulations as Class 8, Corrosive Material. That means that it is automatically classified under WHMIS as a corrosive material. But were there actual data that could be found in the literature to support that classification? I didn't find any. It's a situation which applies to many materials such as maleic anhydride, in which the classification as a corrosive acid seems so obvious that a test for corrosion on metal seems

Robert Whiting *continued*

unnecessary. I expect that it would probably be corrosive to metal and probably be corrosive to animal skin if tested. But lack of definite data is also going to create some difficulties when we come to the toxic category.

Finally we have Class F, Dangerously Reactive Material. Maleic anhydride is normally stable; it is not violently self-reactive. It will, in fact, participate in polymerization reactions, but it will not polymerize on its own. So, even though it might have some violent reactions if it came in contact with incompatible materials, it is not a dangerously reactive material. For example, a reaction with water gives maleic acid, but that reaction is not violent.

There is some indication of violent reactivity by maleic anhydride at elevated temperatures. So the question arose "How high would a temperature have to be elevated and still be regarded as meeting criteria for dangerously reactive material?" In this case, there is violent decomposition at about 150°C if there are traces of a base, such as sodium hydroxide, present. (I assume that means simply relying on sodium ions, because it wouldn't last long as a base in an acid environment.) My inclination is to say that 150°C is too high to be realistic for classifying something as violently reactive, but it is hard to say what the relevant temperature would be. Roughly, we've taken the viewpoint that 100°C, that is the boiling point of water, might be a realistic temperature to take as a cutoff for an unstable compound. It may even be lower than that. For example, TDG regulations take as their reference temperature for such things as decomposition or explosion of cylinders, about 55°C. There may be some room for judgment.

Slide 40

Maleic Anhydride

	Property	Meets Criteria?
D. Poisonous & Infectious		
1. Immediate	LD_{50} (oral g.p.) 390 mg/kg	Toxic
2. Other Chronic	Insufficient Data	---
Carcinogenicity	Not Listed	No
Teratogenicity & Embryotoxicity	Insufficient Data	---
Reproductive Toxicity	Insufficient Data	---
Mutagenicity	Insufficient Data	---
Respiratory Sensitization	Human Data	Very Toxic
Skin Sensitization	Human Data	Toxic
Skin Irritation	Severe	Toxic
Eye Irritation	Severe	Toxic

Now for the toxic categories. Dealing with Division 1, Immediate and Serious Toxic Effects, we have an LD_{50} in the guinea pig of 350 mg/kg, which means that it meets the criteria for "Toxic Material." We find a lot of chemicals which are fairly strong acids or fairly strong bases have LD_{50}s in the toxic range. I'm not entirely sure what to do about that. It seems fairly clear that a corrosive material ought not to be classified as a primary skin irritant, but not as clear that a material which is acting primarily as a corrosive material ought not to be given the skull and crossbones. Nevertheless we've classified it as toxic under Division 1.

In Division 2, Other Toxic Effects, in most subdivisions there are insufficient data to do a classification. This, of course, is a common situation. It's not listed as a carcinogen and there are insufficient data for chronic toxic effects, teratogenicity and embryotoxicity, reproductive toxicity, and mutagenicity. The one area where there seems to be fairly consistent agreement among the experts is respiratory sensitization. The documentation of TLVs, which must be one of our primary sources of information, indicates that maleic

Robert Whiting *continued*

anhydride is a respiratory sensitizer and a skin sensitizer. That is simply given as a fact. We tried to confirm this but could find no indication anywhere in our searches of the literature of any report about respiratory sensitization. We found that many data sheets and reviews call maleic anhydride a respiratory sensitizer. I think that is as far as anyone can go. We have classified maleic anhydride as a respiratory sensitizer, which means that it is very toxic under Division 2 and it would contribute to making the product very toxic. Based on the anecdotal evidence in the literature, it would be regarded as a skin sensitizer.

Maleic anhydride can cause severe skin and eye irritation, presumably due to the corrosive effects of the acid. After discussing this question with Richard this morning and listening to his presentation, I feel that maleic anhydride should not be classified as an irritant but only as a corrosive material. I assume there could be situations in which the skin effect might extend beyond the corrosive effect; for example, if it still existed in the diluted solution, one might still classify a chemical as corrosive and as a skin and eye irritant.

In summary, for maleic anhydride, we have a toxic rating under Division 1 and a very toxic rating under Division 2.

Slide 41

Chloroform

	Properties	**Meets Criteria?**
A. Compressed Gas	Critical Temperature & Vapour Pressure	No
B. Flammable & Combustible	Not Flammable	No
C. Oxidizing Material	Not Oxygen Donor	No
E. Corrosive Material	Stabilized: Not Corrosive Unstabilized: Corrodes Aluminum	No
F. Dangerously Reactive Material	Stabilized: No Reaction Unstabilized: Yields HCl, Cl_2 Phosgene in Air	No

Robert Whiting *continued*

Chloroform is the second ingredient of the product. Fortunately, we are unlikely to find very many products around these days containing chloroform since it can cause a number of serious toxic effects.

Chloroform is not a compressed gas, based on its critical temperature and vapour pressure. It is not flammable; there is no flash point. It is not an oxygen donor; it is not an oxidizing material.

One of the interesting points to do with chloroform and many other chlorinated solvents is that these materials, as commercially sold, are stabilized. In the absence of a stabilizer, it would immediately begin to break down and release hydrochloric acid; the chloroform would corrode aluminum quite readily and meet the criteria for a corrosive material. But the stabilizing material, such as ethanol or methanol, inhibits this corrosive reaction. So it seems realistic to say that commercial chloroform would not be a corrosive material. It would be important to indicate on the Material Safety Data Sheet that if chloroform were stored for a long time or were exposed to air so that the stabilizing effect was depleted, it might become a corrosive material.

Commercially provided chloroform is not dangerously reactive; it undergoes no self-reactions. When exposed to air, unstabilized chloroform yields hydrogen chloride, chlorine and phosgene, even at room temperature and certainly if it's heated. So pure chloroform would have to be classified as dangerously reactive because of its ability to yield phosgene and HCl in significant yield. Since the chloroform is normally provided with a stabilizer which prevents these reactions, my conclusion is that chloroform is not a dangerously reactive material for realistic purposes of use in the workplace.

Slide 42

Chloroform

	Properties	Meets Criteria?
D. Poisonous & Infectious		
1. Immediate	TDG 6.1 Group II	Very Toxic
2. Other		
Chronic	Tumours at Doses < 100 mg/kg/day	Toxic
Carcinogenicity	IARC B TLV A	Very Toxic
Teratogenicity & Embryotoxicity	Effects With Maternal Toxicity	No?
Reproductive Toxicity	Effects With Maternal Toxicity	No?
Mutagenicity	Sperm Abnormalities + In Vivo SCEs	Very Toxic
Respiratory Sensitization	Not Reported	No
Skin Sensitization	Insufficient Data	No
Skin Irritation	Mild or None	No
Eye Irritation	Moderate	Toxic

There are areas in which the toxicity classification of chloroform is very well established and others in which there may be some questions.

In Division 1—Immediate and Serious Toxic Effects, chloroform is listed as Class 6.1, packing group II in the TDG regulations. This automatically means that it is classified as a very toxic material under WHMIS. We went to the literature and looked for LD_{50} and LC_{50} values to support rating chloroform as packing group II, but we didn't find any. In fact the LD_{50} values are in the 100 to 500 mg/kg range, or higher. There is not an LC_{50} value available at all, as far as I can tell. So you will find, in many cases, it is critical to look at the TDG rating and not just at the data, because the TDG regulations themselves are based on professional judgment. The committees that draw up these regulations and

Robert Whiting *continued*

classify these materials at the international level may apply a rating to a chemical which is based on their evaluation of the possible severity of an accident. Possibly a major accident involving a spill of chloroform might cause permanent liver damage or kidney damage or a risk of cancer; and this might justify a more severe packing group.

Under Division 2, Other Toxic Effects, there are some data on the chronic effects of chloroform. Most of these data are available through various tumour studies. Although not everyone may agree, I feel that you should take data which have been used in the evaluation of carcinogenicity and also apply them under chronic effects. These studies on chloroform have been extremely well done, and they are quite consistent in showing that tumours are one of the toxic effects seen in animals exposed to below 100 mg/kg per day. It seems logical, although somewhat redundant, to classify chloroform as toxic under that particular category. The reason is that under the carcinogenicity criteria, chloroform is classified as an IARC carcinogen in category 2B, possibly a human carcinogen, and it is in Appendix A of the TLV list. This means it is regarded as very toxic.

Mutagenicity—there are no chemicals that are known as human mutagens; but chloroform is one of the few that would meet the WHMIS criteria for mutagenicity in vivo. The criteria for classifying a chemical as very toxic in the mutagenicity section are one valid test showing a mutagenic effect on the germ cells and one test showing the mutagenic effect in somatic cells (cells other than germ cells). There is a study showing that inhaled chloroform causes sperm abnormalities in mice. The study dealt with the mutagenicity of various anesthetic agents; and among a group of a dozen anesthetic agents, chloroform was the only substance which caused a significant frequency of sperm abnormalities. Sperm abnormalities is one of the assays which is included in the Health and Welfare guidelines and thus is a mutagenicity test which may be applicable to WHMIS. It is one of the more common mutagenicity tests done on germ cells in vivo.

In addition, there was a test showing an increased frequency of sister-chromatid exchanges, or SCEs in vivo. The sister-chromatid exchange test is not often performed in vivo, but it was done with chloroform. So the combination of those two tests would give a very toxic rating for chloroform in this second category.

The others are more readily dealt with. Respiratory sensitization has not been reported. There are no data on skin sensitization. One would conclude, based on the large amount of exposure there has been to chloroform in the past, that the lack of reports on skin

Robert Whiting *continued*

sensitization indicates it probably isn't a skin sensitizer. There have been several reports on skin irritation; it is reported as being either a mild irritant or not irritating at all. So it would seem not to meet the criteria. There are reports that chloroform is a moderate eye irritant, based on animals studies. One very useful source for these types of data is Grant's Toxicology of the Eye. It is perhaps the most detailed and reliable source of information on the irritative effect of chemicals on the eye. Grant gives numerical ratings for many chemicals.

Slide 43

Chloroform
Reproductive Effects

	Schwetz et al RAT			Murray et all MOUSE		
Conc. (ppm)	**30**	**100**	**300**	**100** **Days 1-7**	**6-15**	**8-15**
Fetal Resorption	-	-	+	+	-	-
Retarded Development	+	+	-	+	+	+
Decreased Size	+	-	+	+		+
Teratogenicity	-	+	NS	-	-	W
Anomalies	-	+	NS	-	-	+
Maternal Toxicity						
Decreased Weight Gain	W	+	+	+	NS	+
Decreased Conception	-	-	+	+	+	-
Increased Liver Weight					+	

I would like to spend a minute on the reproductive effects. In my judgment the reported reproductive effects of chloroform do not meet the criteria. But I think it is important to look at the actual data for this in some detail, because it is not very straightforward to interpret reproductive data. If you were to go to certain compilations of information on chloroform, you would find that some state clearly that chloroform is a teratogen and give two particular papers as references. But the criteria for teratogenicity in various sources are quite variable. The distinctive feature of WHMIS is that it specifies that a teratogenic or embryotoxic or fetotoxic effect must occur in the absence of maternal toxicity. So, it might be called a true reproductive toxic effect. Many chemicals will cause reproductive effects if one disregards maternal

Robert Whiting *continued*

toxicity. If you look under reproductive categories in RTECS, that is the primary type of information you'll get. You'll find many chemicals which have been reported to cause reproductive effects as part of a general toxic response to exposure.

Two studies were done on chloroform, one in the rat and the other in the mouse. One study looked at different concentrations and the other looked at exposure at different times during pregnancy. Both studies looked at a number of different effects in the offspring and in the maternal animals. In almost every category of effects on the offspring, toxic effects were observed. For example, there was fetal resorption, that is, death of the fetuses. One can determine that the embryo was implanted, but at some stage of pregnancy, the fetus died and was resorbed. There was retarded development in most of the study groups; that is, the animals were born small or less developed, in terms of stage of organ development. There were abnormalities, such as missing tails or defects in the eyes. There were some minor anomalies such as malformed ribs, which are not normally regarded as teratogenic effects, but abnormal effects were also seen in the studies. In some cases the effects were slight or marginal and are listed as NS (not significant).

These effects in the offspring were observed in the presence of some significant maternal toxic effects through both studies. Toxicity was measured as decreased weight gain, which is often the only sign of maternal toxicity consistently measured in most studies. In evaluating a study against the WHMIS criteria, it's often maternal weight gain which has to be used as the criterion for maternal toxicity. Maternal weight gain was decreased in both studies. Another effect which occurred at a number of points was decreased rate of conception, which is an indication not of an effect on the offspring, but an effect on the parent. If one had decreased conception in the absence of other toxic effects, that would be regarded as a reproductive effect under the other criterion—reproductive toxicity. But since these effects occurred in the mother and in the offspring in the presence of maternal toxicity, neither would be regarded as meeting the criteria. An additional measure of toxicity in the mouse study was the measurement of increased liver weight indicating that the chemical was causing severe effects on the liver.

Taking these pieces of evidence together, I conclude that chloroform does not meet criteria for reproductive toxicity or embryotoxic and teratogenic effects. This type of detailed analysis is often necessary with this particular criterion because of the lack of consistent reporting of these effects in the literature. Very often, you will have to go back to look at the original study or consult a resource like the Centre which can go back and look at the original study.

Slide 44

Methyl Ethyl Keton

	Properties	Meets Criteria?
A. Compressed Gas	Vapour Pressure	No
B. Flammable & Combustible	Flash Point -6° C	Flammable Liquid
C. Oxidizing Material	Not Oxygen Donor	No
E. Corrosive Material	Not Corrosive	No
F. Dangerously Reactive	Stable	No

The third component of the mixture is methyl ethyl ketone. Almost all of us come in contact with this substance regularly; it is a very common solvent. Its physical and toxic effects are, for the most part, familiar. It is not a compressed gas; it's a very flammable liquid with a flash point of -6°C. Given that methyl ethyl ketone is present in 75% of the product, it may be that the product as a whole is a flammable and combustible material. It is not an oxidizing material. There is no indication that it is corrosive, and MEK is a very stable material. The most interesting information in terms of classification comes up under toxicity.

Slide 45

Methyl Ethyl Ketone

	Properties	**Meets Criteria?**
D. Poisonous & Infectious		
1. Immediate	LD_{50}, LC_{50} Above Cutoffs	No
2. Other		
Chronic	Above Cutoffs	No
Carcinogenicity	Not Listed	No
Teratogenicity & Embryotoxicity	Effects With Maternal Toxicity	No?
Reproductive Toxicity	Limited Neg. Data	No
Mutagenicity	No Animal Data	No
Respiratory Sensitization	Not Reported	No
Skin Sensitization	Not Reported	No
Skin Irritation	Probably Not Irritating	No?
Eye Irritation	Moderate to Severe	Toxic

In Division 1, the LD_{50} and LC_{50} values all exceed the cutoffs, so that MEK does not meet the criteria for immediate and serious toxic effects.

In Division 2, Other Toxic Effects, we find very few categories in which there is even a question of meeting the criteria. Under chronic, the value of the doses which cause chronic toxic effects are above the cutoffs. It is not a listed carcinogen. There are limited negative data of reproductive toxicity. There are no animal data regarding mutagenicity and no report of respiratory or skin sensitization.

There are two areas marked with question marks because the literature can be confusing. I'll deal briefly with eye irritation first. Numerous studies have been done on the eye irritation effects of methyl ethyl ketone. The consensus is that it causes moderate to severe irritation based on the scales that have been used in Draize tests and the OECD Guidelines. It is clearly a moderate to severe eye irritant and meets WHMIS criteria.

Robert Whiting *continued*

The skin irritation classification is less clear. In RTECS you will find citations indicating that methyl ethyl ketone is a moderate or severe skin irritant and on that basis one might be inclined to say it meets the classification criteria. But our experience with methyl ethyl ketone indicates that perhaps it is not really that irritating. So we checked the original data cited in RTECS. There is a particularly illuminating paper about the consistency of tests for skin and eye irritation, which is worthwhile for anyone involved in classification. It is listed as a reference in the MEK CHEMINFO record.

A very large interlaboratory comparison study was done for skin and eye irritation using about 25 different laboratories and about 20 different substances. Each substance was given to the laboratories to be independently tested without knowing what the chemical was. MEK was tested for both skin and eye in this study and the consensus quite clearly was that it was moderately or severely irritating to the eye. But about 16 of the 20 laboratories which tested it for skin irritation said it was not irritating to the skin. Even so, a couple of laboratories reported that it was severely irritating to the skin. That was apparently the basis on which the RTECS record referenced it as severely irritating to the skin.

It is interesting that the authors subsequently took the methyl ethyl ketone, went individually into the laboratories where the result had come out as severe, and had it retested and watched how the test was done. They found that when it was tested in their presence, the results were no longer severe. Unfortunately, we cannot control the data and have materials retested, but it is worthwhile to look at the original data in cases like methyl ethyl ketone where we might otherwise be inclined to bring the chemical into Class D simply on the basis of skin irritation or eye irritation.

Slide 46

Methyl Ethyl Ketone
Reproductive Effects

	Schwetz et al 1974		Deacon et all 1981	
Conc. (ppm)	**1000**	**3000**	**1000**	**3000**
Embryo Toxicity	-	+	-	-
Fetotoxicity (Abnormalities)	+	+	-	W
Teratogenicity	-	W	-	-
Maternal Toxicity				
Decreased Weight Gain	-	-	-	+
Liver Changes	-	-	-	-
Decreased Implantation	-	-	-	-

Dealing with the reproductive effects of MEK, we have a couple of studies which are rather like the ones for chloroform—one by Schwetz et al in 1974 and another by Deacon et al in 1981. In fact, some of the same people were involved in both studies. The 1974 study had reported positive effects for embryotoxicity, fetotoxicity and a weak effect for teratogenicity in the rat and also reported that there was no maternal toxicity. This was quite a surprising result. So the study was repeated and larger numbers of animals were used and more careful analysis done. The result of the retesting was that the embryotoxic and teratogenic effects were not seen. There was some very weak indication of fetotoxicity and abnormalities in development. On the other hand, there was maternal toxicity in this second study at the higher dose. So, if you had only the 1974 study, you would have to classify MEK as a reproductive hazard because the effects seemed quite clear. The combination of the two studies makes that conclusion very questionable. I would be inclined to say it is not a reproductive hazard based on lack of consistent information.

That covers all of the aspects of the classification of the individual ingredients of Material 1. In summary, we have classified maleic anhydride as a poisonous and infectious material, in Division 1 as toxic, and in Division 2 as very toxic; and as a corrosive material. Chloroform is a poisonous and infectious material; very toxic in both divisions. Methyl ethyl ketone is a flammable liquid and a poisonous and infectious material, toxic, based on eye irritation. I also calculated the product LD_{50} based on the lowest available LD_{50} values for each of the ingredients and found the calculated LD_{50} of the product would be 484 mg/kg, which would

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Robert Whiting *continued*

make it toxic. If you choose any value other than the 120 mg/kg for chloroform, it would be well outside the range. The 120 may be an anomalously low value because many are in the 1000 mg/kg range. So the product LD_{50} may not be too relevant in this situation.

Overall the classification of the product is probably a flammable liquid (we don't have the actual test data, but it looks very well as if it might be); it is very toxic in Division 1 primarily because of the TDG rating for chloroform; very toxic in Division 2 of Class D because of carcinogenicity, respiratory sensitization and mutagenicity of the different ingredients; and a corrosive material.

Questions

Geoff Granville

The first comment I would like to make is about chloroform having a stabilizer; without the stabilizer one could ask whether this material could be classified as dangerously reactive. Quite a few materials I've actually handled are prepolymers—butadiene, ethylene, propylene—and many of them have stabilizers. We produce one called styrene, and we are going to be calling styrene dangerously reactive because if the stabilizer gets below a critical amount, it could easily give rise to a low-grade, but real, explosion in a tank or a drum. If the lack of stabilizer is such that you could create a hazardous product that could explode, then we would say that is a good criterion for driving the material into the dangerously reactive category.

My second comment is about whether you should capture a carcinogen under chronic effects—something that produces tumours at less than 100 mg/kg per day. We were scratching our heads about that one three months ago, and we still are. I don't know whether it's right but I don't know whether it's wrong. I think Bob has the very same problem.

Robert Whiting

I think it is not critical with a substance like chloroform which is on the carcinogen list. Where it may be necessary to use this information is with a substance which is an animal carcinogen but is not on the ACGIH list or the IARC list. For example, there have been a lot of tumour studies done on the substances on the NTP (National Toxicology Program) list, including substances not referenced on the ACGIH or IARC lists. The tumour studies may or may not have been positive. You've got that data and you might as well use it.

Robert Whiting *continued*

There are other kinds of data you can use as well. Sometimes studies are done for a few days or a few weeks—a sub-chronic or a short repeated study—which you can't use for acute toxicity categories; but if 10 mg/kg per day was lethal to animals in a week, it would meet the chronic toxicity criterion, even if you didn't go a full 90 days. You couldn't go 90 days because all your animals died.

Geoff Granville

I hope you noticed the detail of Bob's classification. It may be dry, yet all of you will be doing the very same thing yourselves if you're involved in classification. It is a very hard, tedious, tough process to go through. It needs a lot of information. That's why we wanted this classification workshop, because it is so difficult to really go into the details. I hope you noticed the amount of data that is available on MEK and chloroform. It is not the thing you do on one Saturday afternoon between a couple of games on TV. It is pretty heavy. To maintain consistency, you should be talking to other companies, clients, customers, and colleagues all the time to minimize the potential for mistakes. You don't want complete inconsistencies.

Marc Baril

About chronic effects—most of the time the sole study you have is a carcinogenic study done by NTP. We use them now to classify substances even if the result of the study is a reduced number of tumours. That is the only information you have; you use it.

On stabilization, a lot of times dioxane is used as a stabilizing agent. Don't forget that it is a carcinogenic substance. That could create a lot of problems for certain chlorinated solvents unless companies find a substitute. Many stabilized substances will be classified as carcinogenic substances because of the stabilizing agent. This is especially true for trichlorethylene.

Richard Morris

It's worth noting that chloroform was brought in under acute lethality on the basis of meeting Transportation of Dangerous Goods 6.1. If you look for LD_{50} or LC_{50} data, you will discover that there aren't data to support that classification in TDG. One of the questions that comes to mind immediately is why did TDG classify it as a Class 6, Division 1? You have to understand the basis for listing on TDG lists in the first place. A number of substances were not readily able to be captured by TDG criteria, but because they were used in a transfer mode and could generate

Richard Morris *continued*

health hazards, they were simply listed. One of the things we have brought into WHMIS by tying ourselves to TDG is that materials that wouldn't be captured by either WHMIS criteria or TDG criteria will find their way into WHMIS because they are on the list.

The same thing happens for some of the corrosive agents. We noticed that with maleic anhydride. There are a number of substances listed as Class 8 because they are chemically reactive, not because they meet any specific data. If they were tested, they might very well meet it; often the test results aren't there. You can't really confirm these things, which is both an advantage and a disadvantage. In the last two years, many people have asked me why WHMIS doesn't use lists. Other people have said they like the IDL (Ingredient Disclosure List) because they look at the IDL to see if the product is a controlled product. You don't look at the IDL to find out if it is a controlled product. We don't want lists. We want a criteria-driven system so that you can use some judgment to bring things into the system. If a list is used, it's all or nothing. Lists have to be updated all the time; they aren't quite right at any one time. I think that is an important point to realize when using TDG data.

David Gaylor

Bob, once again you gave a most thorough review for our fictitious Material No. 1. Those of us who helped create it weren't devious enough.

Using the calculation for averaging LD_{50}s or LC_{50}s, I would agree with Geoff, in that it's probably of minimum relevance particularly when you think of an LD_{50} or an LC_{50} on animals when you're trying to relate that to humans. Take that another step and say that there are different animals involved. If you take it a step further and say that you are going to average all of these, the relationship as to what could affect humans gets further and further away. So, the calculation, for me, is of minimal importance.

The other thing I thought was very apparent from your presentation was the importance of going back to original data when there is a question. This was very ably presented when you talked about irritation data for methyl ethyl ketone and reproductive effects for both MEK and chloroform. You could go to RTECS and get reports of these effects and stop there. But when you looked into the original papers, it is quite clear that they didn't actually meet the WHMIS criteria. When you have classification of a material that causes problems, I think it is very valuable to go back to the original data to make sure the WHMIS criteria are met.

Articles, Definitions, Policies

Lillian Vine

Thank you very much. The next session is on Articles and the speaker was to be Peter Robson. Peter is the Senior Research Scientist in Du Pont Canada Research Centre in Kingston with responsibility as Corporate Occupational Hygiene Resource for Du Pont's Canadian Operations. He has been involved in the development of the Canadian Workplace Hazardous Materials Information System, WHMIS, since its beginning in 1982. He is a Certified Industrial Hygienist under the American Board of Industrial Hygiene and a Director of the Canadian Registration Board of Occupational Hygienists.

Peter Robson found that he had a conflict on the date of this workshop. The American Industrial Hygiene Association is meeting in San Francisco, and he had committed himself to it. What he did was provide a paper on which you might base your questions and discussion (Appendix 1). At this session in the last workshop, we probably could have spent the rest of the day on questions, because many people had many questions. Many people are struggling with the definition of an Article under WHMIS.

Victor Barker
Occugiene International Inc.

I have a very simple question to anyone on the panel. How would you classify welding rods?

Richard Morris

I think this is a good example. If you will all turn to the first page of Appendix 1, WHMIS Classification of Manufactured Articles, No. 2, there are three criteria that you have to satisfy for a manufactured article. It would have to have a certain shape or design (welding rods have that); its use has to depend to some extent on that shape and design; and under normal conditions of use, it won't release or cause a person to be exposed to a controlled product.

Once a welding rod is being used, it will give off any number of controlled products. So, a welding rod is not a manufactured article. It looks manufactured; it looks like an article. But it does not meet the three conditions.

It is edifying to look at some of the examples given on pages 2 and 3, because exactly the same logic is used as I just used to deal with the welding rod. A metal pipe is intended to convey fluids, and it has a tubular shape for that purpose. During its actual use, it doesn't expose people who are working with it or who are at the end of it drinking the water, to a controlled product. Therefore, it is a manufactured article.

Richard Morris *continued*

A metal ingot has no use in the shape it is except maybe as a doorstop, so it's going to be melted to form other objects which often are going to be manufactured articles. During the act of melting, there are going to be things released. If it is a nickel ingot it may release (under the conditions of melting) materials which are hazardous and controlled products.

Polyethylene film definitely has a shape, the shape has a purpose, and it doesn't release anything as polyethylene film. But, if your job is to seal something in the film, one of the potential problems is polymer fever. I think that would be a workplace specific situation and safety precautions to avoid polymer fever would probably be in place for this procedure.

The final example of the four is polyethylene resin. People have called me directly to ask about their plastic products that were formed into pellets and sold as pellets. Obviously it doesn't have an inhalation hazard or skin irritant or corrosive hazard. If you look at the ingredients that went into forming the pellets, there are a number of controlled products. Once you have formed the pellets, the pellet is pretty innocuous. But it is not the final stage. You don't use pellets except to make other products. Therefore, it falls down on the second condition. And under the third condition, it doesn't necessarily release a hazardous material unless in the process it has to be heated to a temperature at which it can drive off some of these controlled products. A plastic pellet would not be a manufactured article. To exempt it you'd have to look at it from another perspective.

Finally, on page 3 of Appendix 1, there are several examples: a cylinder containing Freon, which is a trademark for fluorocarbon 22; this is a compressed gas in that particular container; but the air conditioner or the refrigerator that has that cylinder on it isn't a controlled product; it's a manufactured article.

Some examples are difficult to understand, such as an asbestos-filled gasket. At the last workshop, we looked at examples of various materials that are formed to certain shapes or that use that shape, but in the process of being used have to be drilled, sawn, cut, or handled in such a way as to release something which could be a controlled product. These manufactured articles, in their own right, then can be captured by WHMIS if they release a product which is of concern, such as asbestos or styrene.

Gary Nash
The Mining Association of Canada

I have a question about Section 2 (iii) in the WHMIS Classification of Manufactured Articles about causing a person to be exposed

Gary Nash *continued*

to a controlled product. Was there any consideration given to the concept of the release of a controlled product that would create a harmful effect? You can have release of a controlled product and there may be no harm at all, such as asbestos cement sheet.

Richard Morris

As I understand it, you're concerned that it is releasing a controlled product, but one which you would normally have to be exposed to for a long period of time; it's not an acute-type hazard.

Gary Nash

There are cases where you could be exposed to it for a lifetime and you still wouldn't be able to measure the effect.

Richard Morris

This is a communication delivery system, so there are not very many of us able to set ourselves up as experts and say "I'm satisfied that if you are exposed for a whole lifetime there will be no effect." There is certainly enough evidence to know that under certain conditions asbestos has generated health effects.

Gary Nash

There could be a number of other materials which would release a controlled product, but in quantities that would not create a measurable harmful effect. I think this is quite likely in many cases.

Richard Morris

According to criterion (iii) "a substance will not be released," a certain element of judgment is involved. If you were releasing styrene at a level that would dissipate and become harmless, you could decide that the levels are not levels of concern. We are not talking about fugitive emissions or trace levels. It has to be a legitimate release as we saw in the case of the welding rods; anyone who has ever been in the same building as someone using a welding rod knows a lot of products are given off; some of them are very irritating and noxious and some are more serious than that. There are interpretations and they do specify that they aren't trace levels and they aren't fugitive emissions. We are talking about legitimate by-products.

Gary Nash

I still think that the aspect of determining an appropriate amount of emission might have been considered in this. Some of the

Gary Nash *continued*

European directives talk in terms of harmful effects and they leave it up to someone else to determine the extent of "harmful."

Richard Morris

A controlled product is defined as one that meets one or more of the hazard classes.

David Sheppard
3M Canada Inc

We make a product called lead foil tape. It's elemental lead with an adhesive on the back. I'm not concerned about the adhesive—it's an acrylate adhesive which is not a problem. It fits the definition as far as shape is concerned. What I am concerned about is the lead because there is skin contact in the application of that lead foil to the substratum that you're going to stick it on. How would you address that as far as the article exemption is concerned?

Geoff Granville

What is the subsequent use of the lead foil once it has been put on the substratum?

David Sheppard

It has a variety of uses, but if you're concerned about emissions of the lead from heat, that is not the intent; the acrylic adhesive would not allow it to be heated to a point where the lead would be any kind of a problem. The only exposure would be skin contact during application and conceivably after.

Richard Morris

When we say exposure, we mean it gets into a space where you can get a respectable exposure. The fact that you can put your hand on it isn't enough exposure. You could get a lethal or toxic dose from some materials just by holding them. I don't think lead is one of those.

David Gaylor

We will be discussing EEC directives later on and maybe that will clarify this question. The experience in the US relates very much to manufactured articles. The same definition is in the OSHA Hazard Communication Standard. In the States, they've had a lot more experience and are trying to define how much of a material would have to be released to limit the use of that exemption. We'll

David Gaylor *continued*

probably follow that kind of experience. There are documents in the US that will help in clarifying the point.

Robert Whiting

The earlier question regarding encapsulated dyes is closely related. Maybe you could bring it up again.

Alan Wright
Canada Colors & Chemicals Ltd

I was worried about colour master batches which can contain 50% lead chromate in polyethylene. How do I write up that one? The lead chromate isn't going to come out, it's well encapsulated and is no hazard at all. We also have PVC compounds, which contain lead stabilizers and there may be master batches in PVC, so they could contain lead chromates, tribasic lead sulfates and such. These formulations also have a lot of the materials in your disclosure list, such as DOP and stearic acid. I don't want to tell everyone what is in the formulation because my competitors will just follow. Some of these mixtures can go out and be used in medical tubing or tubing for pumping food down. The DOP won't come out unless you extract it with ether. What do I do with them? They are very similar to a finished article, but they are pellets and somebody else cooks them up and does something with them.

Robert Whiting

My initial reaction is that since it does not meet the definition of a manufactured article, it will probably have to be treated as a controlled product, based on the presence of ingredients such as lead chromate. Possibly an argument could be made in terms of solubility or bioavailability, but that may depend on actually testing that material.

David Gaylor

We have the same problem with polyethylene resins containing controlled products, and we have to treat them that way, in spite of the fact that those controlled products cannot be released. With the given rules, there is no way around it.

Alan Wright

So, after several years of changing formulation in PBC to get a lower-cost product, I have to give it to my competitor? I have about 6000 formulations.

David Gaylor

There are trade secret provisions. We hope to learn that there can be generic claims that will help.

Victor Lopez

Under "Examples" on page 3 of Appendix 1, I am confused by the first example. It says "Stainless steel piping is a manufactured article because it does not release metal during normal use of conveying fluids." Is it not reasonable to consider normal use of a stainless steel pipe would include welding the pieces of that pipe to make a larger pipe? That stainless steel pipe could then perhaps be releasing chromium or other materials. Is this a situation where the rod is not an article but the pipe is?

David Gaylor

This question was brought up in one of the many teleconference calls we've had. The consensus was that the installation is not included in normal use.

Victor Lopez

I don't know of any law or regulation that would be perfect, so I would assume that in the development of WHMIS it would be accepted that there would be isolated examples where the system does not work. Wasn't this the underlying philosophy?

Richard Morris

I don't think anyone that was part of the development of WHMIS thought we were building the perfect system. Three quite separate jurisdictions were involved—the chemical industry, the labour unions, and the regulators. We have had to develop a product that is acceptable to all three groups and still be compatible with TDG, OSHA and EEC. I think we all expect it will take a couple years to fine tune, but there is no reason to throw out the entire system if we happen to find some products that fall between the cracks.

Basil Darrah
Society of the Plastics Industry

As a hypothetical case, if someone used expanded polystyrene board stock for installation and I were to do a literature search and found a report on the release of styrene at 5 ppm, how do I relate that to whether it would be a harmful exposure or not? Can I use a TWA of 50 ppm and say because it's only 5 ppm, it's acceptable or is there a different guideline for consumer products?

Geoff Granville

The first aspect is the actual content of styrene within the expanded polystyrene. You have to determine if styrene is controlled as a pure material in a mixture at 1% or 0.1%. If you look it up you will probably find that styrene is going to be controlled at 0.1%. So if your material contains more than 0.1% styrene, that expanded polystyrene should be a controlled product.

If it is less than 0.1%, can you under normal conditions off-gas sufficient styrene to create a hazard? To determine if a hazard is there, you have to use professional judgment. If it is something like asbestos (and this is something like one fibre per 15 years) you are likely to consider communication. For something like styrene, it's how much for how long? You'll look at the time-weighted average as part of the equation you will go through. If it's going to be 5 ppm for 5 hours and then it starts tapering off, I don't think you should need to communicate that hazard. But if you're talking a mean of 25 ppm in a typical room containing typical levels of expanded polystyrene for a few weeks, then yes, maybe you would. You would do what you think is right.

Classification of Material 2

Presenter: Marc Baril
Chairman: David Gaylor

Lillian Vine

Marc Baril will classify Substance 2.

He obtained a degree in biochemistry from l'Université du Québec à Montréal, a Master's degree in analytical chemistry from the same university, and a doctorate in pharmacology-toxicology from l'Université de Montréal, where he worked with Jules Brodeur.

From 1977 to 1979, he worked at the Quebec Ministry of the Environment as a toxicologist. In 1979-1980, he was a consultant with the Community Health Department. Since 1980, he has been with the CSST (Commission de la santé et de la sécurité du travail du Québec), where he is Director of the Toxicological Index.

After Marc Baril's presentation, please ask questions or comment on the two classifications.

Marc Baril

Product 2 is very different from Product 1. In any case, what we are attempting to show here is essentially a method of classifying chemicals, a method which takes into consideration the cost inherent in the classification and the time required to carry it out. Since most of you come from industry, you will be aware of the importance of classifying substances right from the start, since such classification implies considerable cost in terms of labels as well as data sheets.

Slide 47

Material #2

titanium dioxide	98.40%
crystaline silica	1.50%
zinc chromate	.05%
lead chromate	.05%

The mixture to be classified is made up of titanium dioxide, crystalline silicas, and two chromium salts with concentrations of less than 0.1%.

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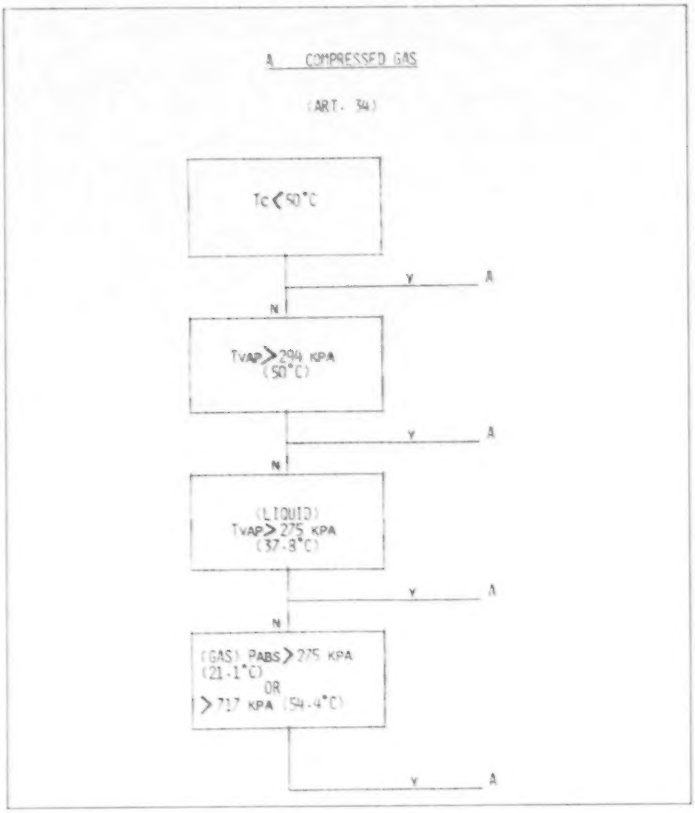

A COMPRESSED GAS

(ART. 34)

Tc < 50°C

TVAP > 294 KPA
(50°C)

(LIQUID)
TVAP > 275 KPA
(37.8°C)

(GAS) PABS > 275 KPA
(21.1°C)
OR
> 717 KPA (54.4°C)

If we look at the classification for Class A, it is clear that we have adapted the law for classification purposes by selecting those criteria for which data are easiest to obtain. It is normally quite easy to find the critical temperature of a gas in the literature, but data concerning 275 kPa at 21°C, that is, the absolute pressure, or 717 kPa, are normally not found in the literature. So it is much easier to go looking directly for the critical temperature. The decision tree is very easy to use: when the critical temperature is lower than 50°C, the substance is automatically considered a Class A substance.

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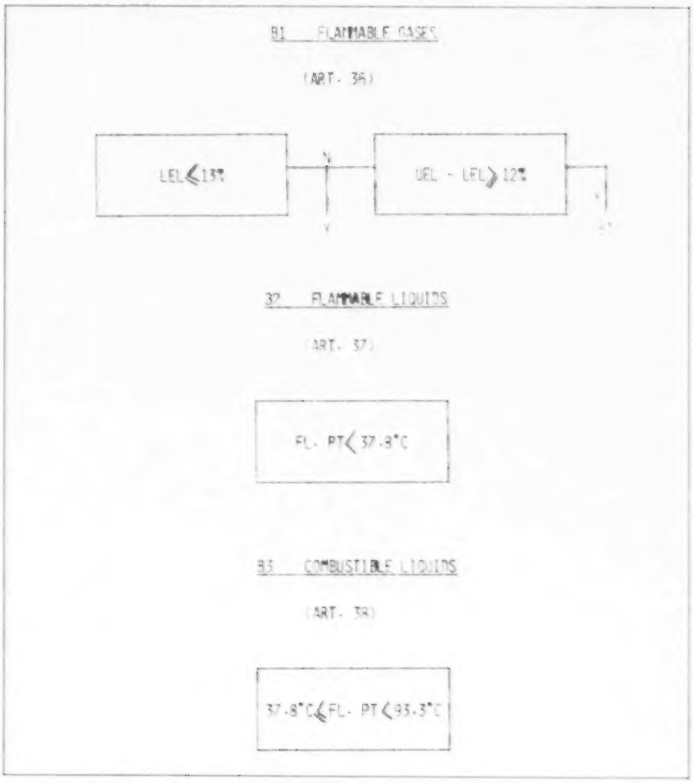

B1 FLAMMABLE GASES

(ART. 36)

$LEL \leq 13\%$

$UEL - LEL \geq 12\%$

B2 FLAMMABLE LIQUIDS

(ART. 37)

$FL.\ PT < 37.8°C$

B3 COMBUSTIBLE LIQUIDS

(ART. 38)

$37.8°C \leq FL.\ PT < 93.3°C$

The same is true for Class B substances: the LEL value is easy to obtain, and if it is negative, one automatically looks for the difference between the upper and lower limits. Normally, these types of data are easy to find in data bases such as CHEMINFO or the CSST's Toxicological Index data base. There is also NFPA, but here one must be careful. NFPA does not distinguish between the upper or lower flammable limit and the upper or lower explosive limit, and I think this is an important distinction. Of course, a substance cannot be classified B1 unless it has first been classified A. (This is just a little notion derived from the law.)

It is relatively easy to obtain the data necessary for a B2 or B3 classification. The type of data necessary for B2, B3 and B4 can always be found in the data banks, either the Canadian Centre data banks or the CSST's Toxicological Index data bank.

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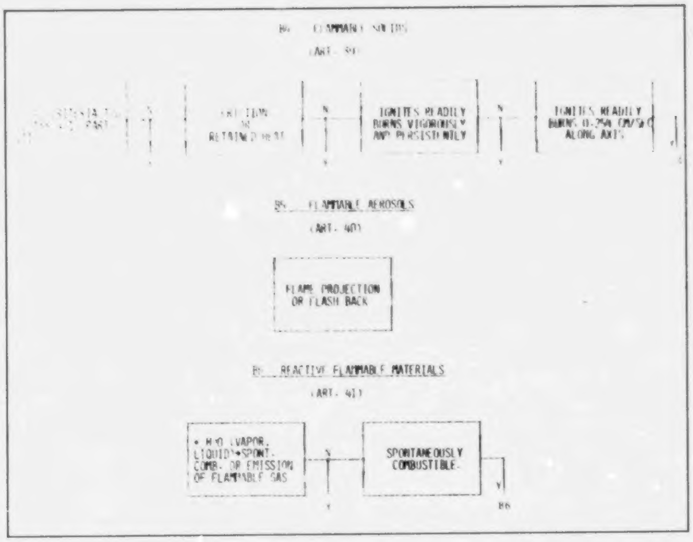


B4 FLAMMABLE SOLIDS

(ART. 39)

[illegible]

FRICTION OR RETAINED HEAT

IGNITES READILY BURNS VIGOROUSLY AND PERSISTENTLY

IGNITES READILY BURNS 0.254 CM/SEC ALONG AXIS

B5 FLAMMABLE AEROSOLS

(ART. 40)

FLAME PROJECTION OR FLASH BACK

B6 REACTIVE FLAMMABLE MATERIALS

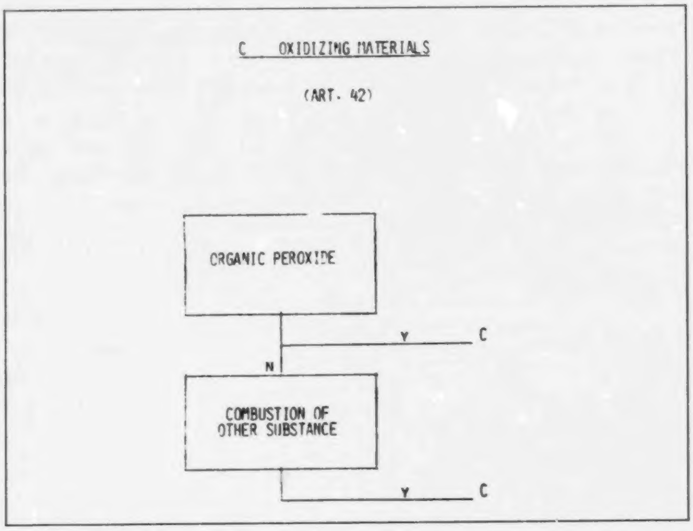
(ART. 41)

+ H2O (VAPOR, LIQUID)→SPONT. COMB. OR EMISSION OF FLAMMABLE GAS

SPONTANEOUSLY COMBUSTIBLE

But there is definitely a problem with B4 when we must push the classification process to the limit and determine whether the substance is burning rapidly at 0.254 centimeters a second. If any of you ever find a data base or a book containing this information, I would certainly appreciate your giving me the reference. There is no difficulty for aerosols either. The same holds true for B6. In all cases, Substance 2 is missing. We always have a negative result.

Slide 51



C OXIDIZING MATERIALS

(ART. 42)

ORGANIC PEROXIDE

COMBUSTION OF OTHER SUBSTANCE

Marc Baril *continued*

For oxidizing agents, we can use our decision tree. With a good knowledge of chemistry, it is relatively easy to determine whether a substance is an organic peroxide. Otherwise, it is always possible to use CHEMLINE or software such as DARC to try to get an idea of a substance's chemical structure.

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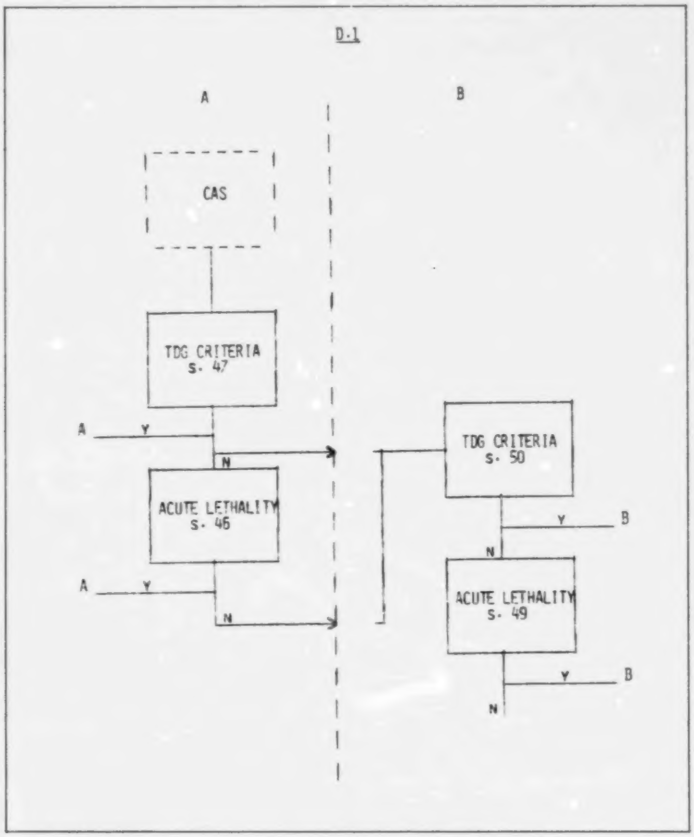
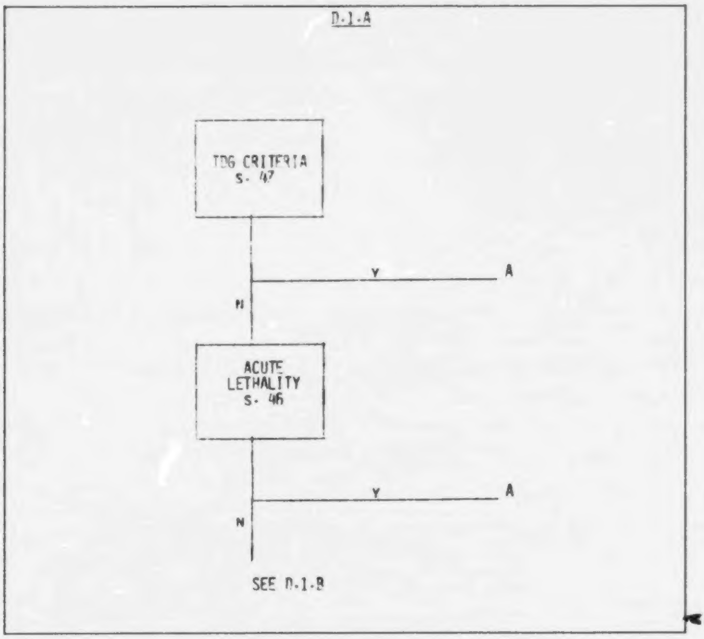


Everything becomes much more interesting once we arrive at Class D. Here, practically speaking, the classification can consider several parameters almost simultaneously. First the TDG criteria must be considered, then the acute toxicity data. The TDG criteria for D1B, which are relatively similar, can be considered at the same time. And when gathering data on acute toxicity for D1A, data for D1B can be obtained too. Normally, the RTECS data base is the only place where this type of information on acute toxicity can be obtained. But as Bob Whiting mentioned earlier, it is very important to check the source of the information given in RTECS, that is, the article in which the data appear, because much of the

Marc Baril *continued*

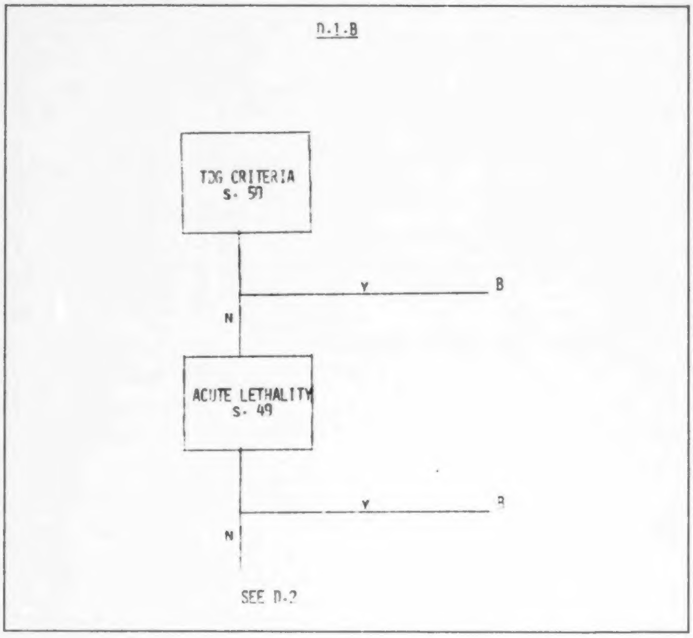
information in RTECS is of very poor quality. If a classification is based solely on RTECS data, I am sure substances will be classified which should not be classified at all. I think the time spent looking for a source article can be a real investment, because if, based on a scientific article, there is no need to classify a substance, you automatically save the cost of producing labels and technical fact sheets. And I'm sure I don't need to remind you of how significant that cost is.

Slide 53



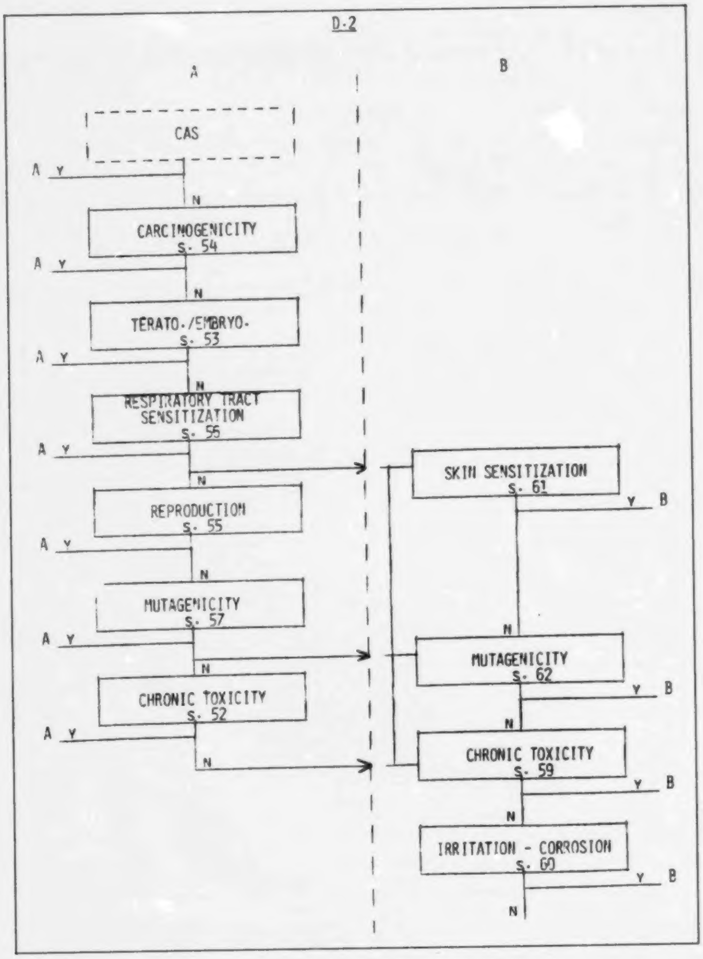
Let us take a closer look now at D1A. We should mention here that the law excludes the gases from Division 4 of Class 2 from Part 3 of the TDG. This is a little detail which we tend to forget—with obvious results.

Slide 54



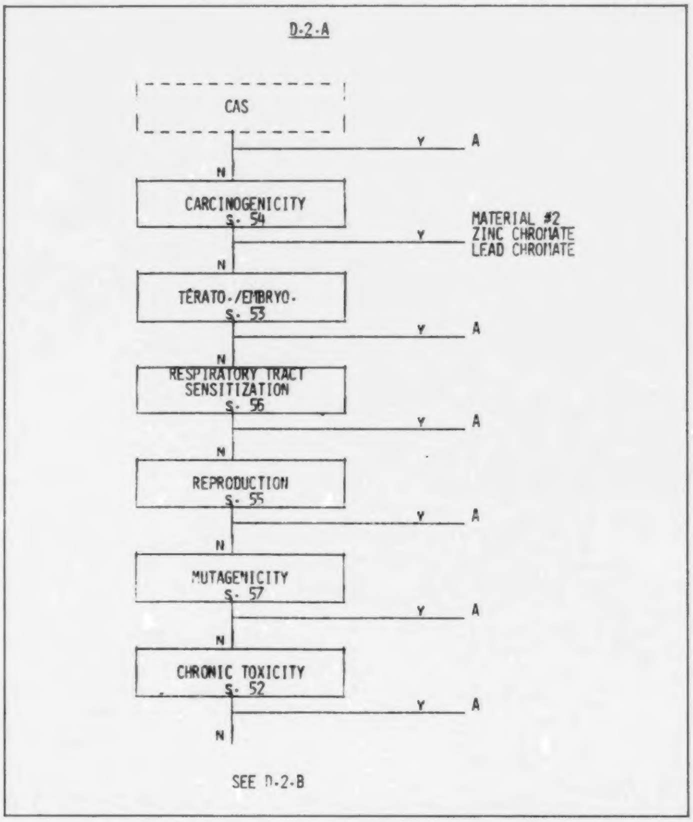
The same is true for D1B. Again, as I mentioned, RTECS is the basic source of data, and our Substance 2 is still missing; there are no positive data on it to be found.

Slide 55



However, in the case of D2B, things are now becoming much more interesting. As I mentioned at the beginning, the decision tree was designed to facilitate the classification of a substance; we can stop the whole process as soon as we obtain a positive answer. The method has been tested. Right now, between 800 and 1,000 substances have been classified in the CSST's Toxicological Index; this amounts to an average of 25 substances per week per person.

Slide 56



D-2-A

CAS

CARCINOGENICITY
S. 54

MATERIAL #2
ZINC CHROMATE
LEAD CHROMATE

TERATO./EMBRYO.
S. 53

RESPIRATORY TRACT
SENSITIZATION
S. 56

REPRODUCTION
S. 55

MUTAGENICITY
S. 57

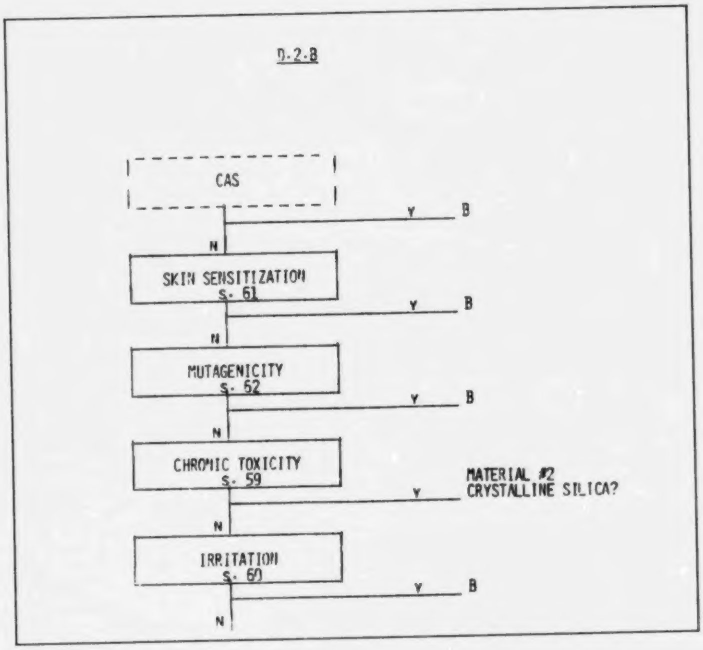
CHRONIC TOXICITY
S. 52

SEE D-2-B

As far as carcinogenicity is concerned, Substance 2 is positive because chromium salts are recognized as carcinogens and are listed as such. Teratogenicity/embryogenicity, mentioned this morning as a major problem, is easy for us because this information already appears in the Toxicological Index data base. This saves us a lot of time. In addition, within a few weeks, we expect to be producing and making available a list of teratogenic agents.

Sensitization. There is a problem here which was not mentioned this morning; namely, that the law mentions sensitization in the workplace. This has caused certain problems. Information on reproduction and mutagenicity is basic. Information on chronic toxicity can normally be found by using HSDB, which for the uninitiated means "Hazardous Substances Data Base", or data from the National Toxicology Program in the United States and, in particular, the IEPA Draft Assessments, which are important sources of information in this area.

Slide 57



D-2-B

CAS

SKIN SENSITIZATION
S- 61

MUTAGENICITY
S- 62

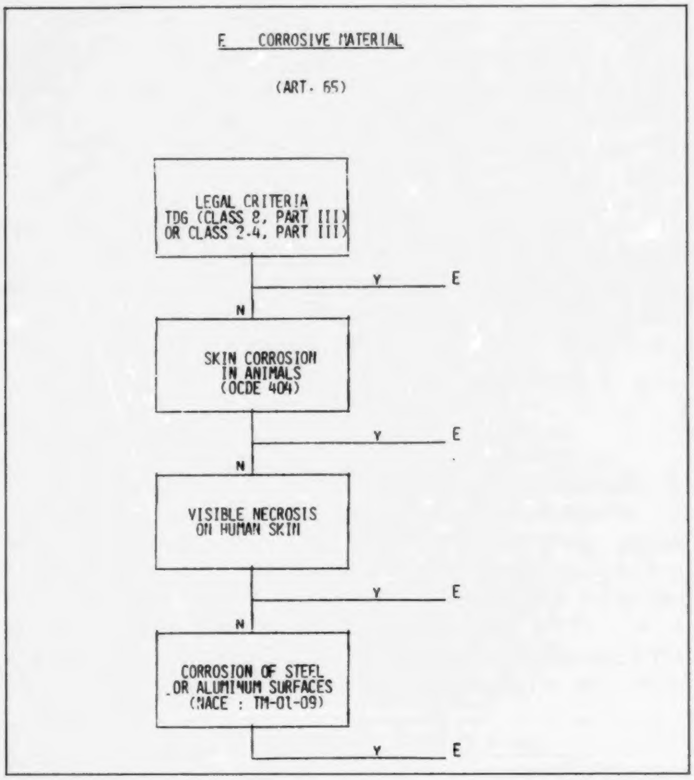
CHRONIC TOXICITY
S- 59

MATERIAL #2
CRYSTALLINE SILICA?

IRRITATION
S- 60

D2B - Our product does not cause skin sensitization and it is not mutagenic. As far as chronic toxicity is concerned, the data in the literature cannot be used for silica because the studies are very poor and were not carried out according to OECD criteria. But, as you all know, silica causes pneumoconiosis and on this basis must be classified as D2B.

Slide 58



E CORROSIVE MATERIAL

(ART. 65)

LEGAL CRITERIA
TDG (CLASS 8, PART III)
OR CLASS 2-4, PART III)

SKIN CORROSION
IN ANIMALS
(OCDE 404)

VISIBLE NECROSIS
ON HUMAN SKIN

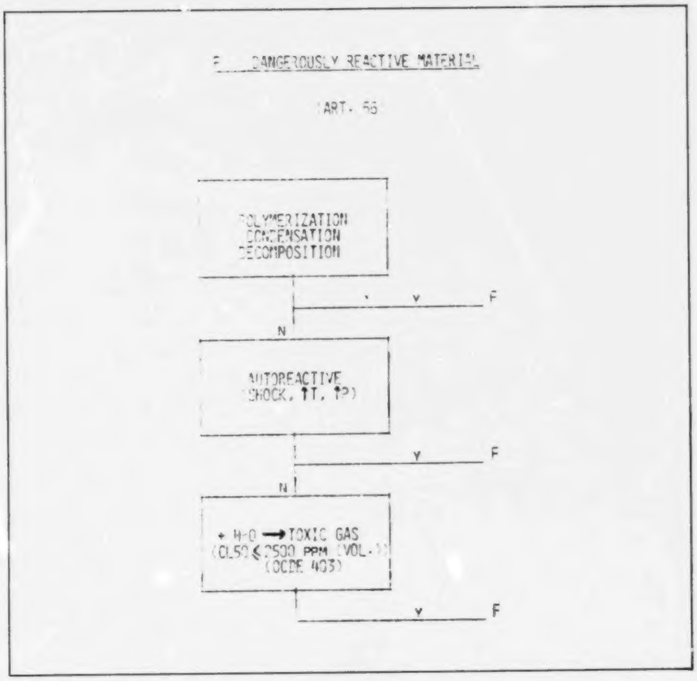
CORROSION OF STEEL
OR ALUMINUM SURFACES
(NACE : TM-01-09)

Corrosive Material, Class E - This is what we have legal criteria for. Skin Notation - Skin corrosion of animals or humans and, if all data are negative, corrosion of steel or of plated aluminum surfaces in accordance with NACE: TM-01-09. If ever you are lucky enough to obtain the necessary data, I am sure all those present who are responsible for classification would be very interested in your sources of information.

Lastly, dangerously reactive chemicals — This does not apply to Substance 2 and normally this type of information can be found either in HSDB, CHEMINFO, or the Toxicological Index data base. Auto-reactivity is the only problem, being relatively difficult to determine.

In the presence of water, gas is produced. As for statistics, a general search through RTECS and the literature shows that only about forty gases fall within the WHMIS criteria.

Slide 59



F. DANGEROUSLY REACTIVE MATERIAL

(ART. 56)

So, to summarize, our Substance 2 can be classed as "D" on the basis of the carcinogenicity of the chromium salts and of the known effect of silica on humans.

Questions

David Gaylor

There are two very key questions to answer. One is if you have less than 0.1% of material that would normally meet the criteria and you have two materials that really meet the same criteria, can you or should you add those? I think there are three things you have to consider. Since the regulations clearly say that you don't have to consider it if it is less than 0.1%, theoretically you can get away with not considering this question at all. But you have an opportunity to exercise some professional judgment. I would consider first whether the two materials have the same effect and whether they affect the same target organ or system. In this case, lead and zinc chromates are considered carcinogens and act in similar ways. You could consider them affecting the same target organ system with the same kind of effect.

Then you should consider the use the product will be put to and the likely exposure during normal product use. You have some leeway and can exercise more professional judgment. Although

David Gaylor *continued*

the first criterion is met, before I would automatically add these together to get more than 0.1%, I would consider how likely it is that people are going to be exposed to this in normal product use. Since we don't know what this product is, I really can't answer that question.

The third important point concerns crystalline silica, which hasn't been tested in animals and therefore doesn't meet the chronic toxic effect criteria. Human data shouldn't be ignored and in fact are very important to consider. Therefore, crystalline silica would easily be classified under the chronic toxic effect class if you consider the human experience.

Marc Baril

Crystalline silica has been tested by instilling the product directly into the lung or other organs, so that there is no correlation directly with the criteria. If you break down crystalline silica into its different components, you could have four or five different silicas under different names. For example, 0.7% of quartz, and so on. It will all be less than 1.0% and will disappear. We have seen some Material Safety Data Sheets using that approach because there are companies already producing them following the new rules.

Robert Whiting

About professional judgment in respect to skin sensitization, there are no data on either of these two chromates causing skin sensitization themselves. In fact, there are scarcely any data on an individual chrome compound causing skin sensitization. But it is well known that chrome compounds added to cement, for example, do cause skin sensitization. If the chromium compound is present at a higher concentration in the product, I would be inclined to classify it as a skin sensitizer based on the judgment that this compound could cause a sensitization reaction.

Richard Morris

Crystalline silica is a silicon dioxide. There are many products on the market that contain silicates which are obviously mixtures of SiO_2 and a variety of other metals. I have come across a concern about labelling a product that contains more than 1% silicates, of which some is silicon dioxide. One has to look very closely at the chemical composition and the impact it will likely have on a mixture of ground silicates and other substances to form a cement product. This certainly is an area for professional judgment.

Richard Morris *continued*

As far as adding of carcinogens, one has to consider what the target organ is and in what way the potential carcinogens are likely to be added or how they will interact. In this particular case, it was chosen quite specifically; it is legitimate to add these chromates together. It becomes more confusing when you start adding nickel salts (on which there are no data at all). According to IARC criteria, certain nickel salts would be considered carcinogens. These types of materials are on the list, but you have to use some professional judgment. You may have to use that judgment for classification, but when it comes to communicating hazards, I think you have to specify that the material is on the list without disclaiming it and indicate why you feel that your product will not expose the workers to a carcinogen.

Erich Krayer
Hoechst Canada Inc

If your CCINFOdisc is up and running with your PC and your optical disc reader, how far along the road are you to classifying a substance completely if you only have that information on that system? Also, what other books, libraries and other sources of information would you need to do a complete job? And, how far would you pursue these other sources, appreciating that you would like to do a complete job on a classification but you can't spend a long time doing one product at the risk of neglecting other products?

Robert Whiting

I hope that you would find many of the chemicals in CHEMINFO. If not, I doubt that the data bases on CCINFOdisc alone are sufficient to classify most chemicals. RTECS and NIOSHTIC are excellent routes into the literature. With the abstracts from NIOSHTIC, you can get a very good idea of the toxicological test results. Data bases such as RTECS and NIOSHTIC have little data on classes other than D. Some information on compressed gases, flammability, oxidizing properties, reactivity, and corrosion properties is available in reviews, criteria documents and data sheets indexed in NIOSHTIC. The documents are available on microfiche from the Centre on request. That will take a little extra time, but it is necessary. Much physical and chemical information is available in books. I have included in the package a list of about 30 basic information sources. You will need several of these for routine use.

Another excellent source of information is your raw materials supplier's data sheet. It is very difficult to say you can go to any single data base or to a combination of a few data bases and always come up with a classification.

Erich Krayer

If you take Material 1, and assuming a lower level of skill and practice than you have in doing this kind of work, what would you estimate as the number of hours required to classify such a product?

Robert Whiting

The classification of a product could take anywhere from an hour to a week, depending on how much detail you want to go into and how similar your products are. If you are dealing with a lot of chemicals which are closely related, you can deal with them as a family of chemicals with properties in common. They could be classified very quickly. It might take you four days to do the first one, but you might be able to do the others in an hour or two, once you have established your base of knowledge.

Erich Krayer

Our friends south of the border say that there are no free lunches. Well there is one lunch that is just about free and that is CCINFOdisc. It's a small price, and a small investment in an optical disc reader, assuming you have some sort of PC in-house. We bought it six months ago and now have this incredible store of information available. It is really a great leap forward in terms of being able to make some sense of this maze of contradiction and heavy and hard work that is facing most of us right now.

Sylvie McAuley

Why do we all have to classify the same material? Why couldn't a list be formulated to classify the raw materials, such as xylene, toluene, IPA, and methanol, and have that one classification standing, rather than have each company classify the same chemical and end up with different classifications?

Geoff Granville

At the last workshop, we said industries, associations, and sectors should get together to do just that. There were a few problems. Until recently, industry did not want to know. That includes my company as well as others; one is too busy doing a normal job and does not realize the complexity of WHMIS. That's why we have held these workshops.

Government will not do it for us; industry groups have to get together to do it. It has been happening; in the last two months there have been a number of meetings of various associations. Unfortunately, some companies are further advanced than others. I'd like to point out that most commodity chemicals are produced

Geoff Granville *continued*

by a limited number of producers; it should be those producers who get together to do the basis for classification, which will then drive the secondary suppliers and the mixers and the formulators. If there is going to be any working together, it's got to happen quite soon. All I can say to you is go out there and talk to your industry associations. If you're a major supplier, talk to other major suppliers about the context. By and large, there should be similarities; but there will be occasions when different companies will see things differently. What we are trying to do is to minimize those differences and maximize the consistency.

Sylvie McAuley

The Hazardous Products Act states: "No supplier shall sell to any person a controlled product intended for use in a workplace in Canada unless the following criteria are met:..." One of the criteria is if the chemical identity and toxicological properties of any ingredient are not known to the supplier, the concentration of the ingredient must be disclosed on the Material Safety Data Sheet, the label, or whatever. If I have a Material Safety Data Sheet from my suppliers that doesn't give me any toxic information, and I've contacted them and they've said that the data are not available, would that product automatically become controlled and have to be disclosed on my Material Safety Data Sheet?

David Gaylor

Before those rules apply for disclosing ingredients on your Material Safety Data Sheet, the product itself has to be a controlled product. You have to go through the classification process first. When you go through the classification process, if there is no information on the material which would make it a classifiable material, you don't have to worry about disclosure because the whole product is not a controlled product. Do your classification first, and once you've decided it's a controlled product for some reason, then worry about the Ingredient Disclosure List.

Sylvie McAuley

This comes back to the amount of resource material that is available to smaller companies. I've researched the medical library in our town and the Patty's Industrial Hygiene and Toxicology books that I've been able to get are not the most recent. I have already found some controversies in them as to what is known and what is being written down. How deep must I search to find that no toxicological data have been written? It certainly would be handy if there was a list to say what has already been researched and the classification, so we could apply it to our finished product.

Geoff Granville

There are about 40,000 to 50,000 chemicals in commerce in Canada. Put together the number of formulations and mixtures of 40,000 chemicals and you are talking about close to a million. It is not easy to compile a list. I agree it would be a super thing to have, but you're unlikely to have that for anything but the 200 or 300 big building block chemicals within the next few years. We just won't have it.

Robert Bouchard
Fédération des travailleurs du Québec

My question is addressed to Mr Whiting and concerns his professional opinion about chloroform and methyl ethyl ketone as regards the reproductive effects defined in article 55 of the regulations. There is said to be reproductive toxicity if there is proof that the substance or chemical causes sterility or has harmful effects on a worker's reproductive capacity following occupational exposure.

It seems to me that when a child is born with a below-normal birthweight and certain abnormalities, there is justification for supposing that there have been reproductive effects. I was surprised to see that in the table you presented for chloroform, there were 11 little crosses indicating positive results out of a possible total of 21, that is, more than 50%. And yet in your evaluation, you stated that there are insufficient data to constitute real evidence or that the studies are inconclusive. It is important for practitioners like me and my colleagues in the trade union movement in Quebec, who must apply the right to preventive withdrawal of pregnant workers, to have access to such information. I hope that when professional opinions such as this one are given, and if the scale tips only very slightly to one side or the other, the benefit of the doubt will lead to more information.

Often, the female worker is exposed to other contaminants and constraints, such as physical and economic constraints, which weaken her metabolism, her constitution, and her ability to withstand the toxic effects of toxic substances. As far as we are concerned, when we find traces of these substances in the ambient environment, we have absolutely no hesitation about exercising our right to request preventive withdrawal and about encouraging women to exercise theirs.

It is all very well to speak about a professional opinion, but workers will certainly face an uphill climb if the studies on which the opinion is based are not referred to on the analysis sheets.

Robert Whiting

When evaluating criteria such as those to do with reproductive effects, you have to examine why those criteria exist. There are two kinds of criteria in the system. Criteria such as acute and chronic toxicity are based on specific doses of chemicals causing an effect in animal studies; they can be used to catch chemicals having any toxic effect, whether it be a reproductive effect or a nervous system toxic effect. These criteria operate for all effects that the chemicals are capable of causing at a certain dose.

The other kinds of criteria are those which apply to the reproductive effect and also to carcinogenicity in which there is a reference dose or an upper limit given. They exist to catch chemicals which exist outside the dose range but about which there may be a special concern. It is generally true that any chemical if given in a large enough dose will cause reproductive effects. The purpose of the WHMIS system is to identify those chemicals which are specifically reproductive hazards within the reproductive criteria. So we need guidelines to evaluate the reproductive effect which is not redundant with other effects, such as dose, but which can identify chemicals which are very specifically reproductive hazards, such as thalidomide. The reason thalidomide and certain other chemicals are so feared is that they can cause reproductive effects in the absence of toxic effects in the mother. This criterion exists specifically to catch that kind of chemical.

When evaluating a chemical such as chloroform or MEK, a number of reproductive effects will be identified. If these effects occur at doses that were sufficiently low concentrations, that chemical would meet the chronic toxicity criteria or the acute toxicity criteria anyway, and it would already have been caught. We want to find those chemicals which cause toxic affects specifically on the offspring or that specifically effect the reproductive system. The guidelines exclude any chemical which causes another type of effect, for example maternal toxicity, at the same time as it causes toxicity to the offspring. These criteria are set up so that you must have "valid evidence" that the effect on the offspring occurs at a dose which does not cause harm to the parent. It is clear that chloroform does cause toxic effects in the parent; but, one study found that MEK does cause maternal toxic effects and another study found it doesn't. There is also a matter of bias in the way these studies are run in that there may be 20 parameters examined for toxic effects on the offspring and one parameter examined for toxic effects in the parent. It is possible to have many different kinds of toxic effects which are of a debilitating nature wherein you might see one toxic effect in the parent because that happened to be the only thing that was measured. Maternal toxic effects, such as weight loss or liver damage, are very major effects.

Robert Whiting *continued*

Having said all this about the classification system, I would make a different point about information. It is very important that the information on chloroform or MEK exists. That a study found reproductive effects and there is some limited information that it might be a reproductive hazard must definitely be communicated. I would differentiate between classification and communication. We want classification to be as precise as possible regarding the criteria, but in terms of information, all the data must be communicated to give the limitations of these studies, so that the extent of possible hazard in the workplace can be understood.

Victor Lopez

The criteria lend themselves to the development of a computer program with an interactive approach where the machine would ask certain questions and by inputting certain data, you will be able to have a large part of the work of classification done. Do you know if such a program exists here or in the United States, or if one is being developed?

Marc Baril

No, there is no such a program because any data bases available now in North America or Europe cover only a very small part of the science. You would have to integrate a different data base and very few of them are factual data bases. CHEMINFO from the Canadian Centre for Occupational Health and Safety, HSIB from the medical library in the US, and our data base at the CSST are factual data bases. The bibliographic data bases are updated and can help direct you to the source information, but nothing else. By just using the computer you wouldn't be able to classify.

As Bob mentioned in his presentation, RTECS, which was the sole data base for obtaining LD_{50}, has no quality control. So you could find a lot of information but also a lot of garbage. You have no choice; you have to go to the article and discard the data. If RTECS gave you an LD_{50} over 2000 mg/kg, you don't have to look further. But if it is on the borderline, you have no choice but to go to the article. As I mentioned in my presentation, it is very important to go through the article. At least by classifying the substance, you can use the information to produce your Material Safety Data Sheet.

David Gaylor

There are companies using computer systems to generate a Material Safety Data Sheet from standard expressions that are automatized. The actual information that goes in and the choices of information

David Gaylor *continued*

that actually go on the data sheet has to touch human hands. And it should be reviewed. There are systems that produce data sheets that go out to the customer without anyone seeing them first. You might be wise to look at the final product your computer produced for you.

Hans Iwanowsky
Kingsley & Keith (Canada) Inc

I'm confused. I presume that Material 2 is a man-made mixture. Are mixtures with ingredients that have to be disclosed always man-made? And conversely, if complex mixtures are natural or pure substances, would the natural contaminant of, for example, 0.4% arsenic have to be listed as an ingredient in a controlled product? Or would it make an uncontrolled product a controlled product?

Marc Baril

Material 2 came from the minds of Peter Robson and Geoff Granville, so there is no contaminant or natural contaminant like arsenic in it. You may face that problem but it will be considered a mixture, as crude oil is considered a mixture. You won't be able to deal with each natural contaminant. It will be a general product and will be listed.

Geoff Granville

We are having a debate in part of the petro-chemical industry about this right now. When you are talking about a complex mixture out of a refinery, there are at least two possible extremes of approaches. One is, even though you know it is a complex mixture, you often have a lot of technical details about that mixture to provide appropriate information based on your knowledge of the composition. So if the product is a light boiling naphtha that you know contains benzene, toluene, and xylene, you may put down ingredient disclosure and give tons of information based on those three ingredients. That's one extreme.

The other extreme is to say it's a complex mixture; you do not need to disclose the ingredients, which is correct according to the word of the law. Whether or not you disclose ingredients, what about the information that is the basis of your classification? If that material, or a very similar material, has not been tested for various end points, such as carcinogenicity if you're talking about benzene, whether or not you disclose the benzene content, professional judgment dictates that if you know benzene is in the light naphtha at above a critical point, that material has the hazards

Geoff Granville *continued*

of benzene for carcinogenicity. You will end up with some certain light boiling complex mixtures with the assumption that the material was pure benzene. Whether or not you put the words benzene, toluene, etc., on the Ingredient Disclosure List will probably be an individual decision within a company.

Hans Iwanowsky

Is an ingredient something which is man-made and added, or is it what naturally occurs as a by-product or contaminant?

Geoff Granville

You have a definition of a mixture and a definition of a complex mixture. Complex mixture is defined as a naturally occurring product or a process thereof. A mixture is defined as a deliberate addition of two or more components.

Dennis Purton
Caledon Laboratories Ltd

What does classification really generate? You are not necessarily obliged to pass that information along to me, and I have to regenerate a whole classification because of that. That doesn't give us any method of determining how that material will have risk phrases attached to it, what kind of risk phrases will be attached, or how to handle this material in a continuous form from company to company. It just says we're classifying it, we're giving it some kind of nature and characteristic, but it doesn't really benefit us in a lot of ways to pass information along. The safety data sheets are already done and they have their own information.

Geoff Granville

The first thing that is done in WHMIS is to classify materials. It is the drive of the whole system. It will then either fall out and not be classified, or it will fall in and become a controlled product. Once you've done that, everything else follows. You do your trade secret, the confidential business information aspect, only because the material controls it. If it isn't a controlled product, you don't worry about disclosure. You then go through the other three aspects of the container labelling, the MSDS as a supplier or an employer, and the worker education. Classification is all-important; it drives everything. Classification tells you what phrases you have to put on your labels. The interpretation of the WHMIS regulations says whatever class a material is classified under, you have to put down a risk phrase that is appropriate to it. If you have a carcinogen, you will say "Risk of Cancer" or words to that effect. You won't

Geoff Granville *continued*

just say "Possibility of Effects." That is not communication. If you have a corrosive, you will say "Corrosive"; if you have an irritant, you will say "Irritant." You will say the words.

Classification also drives an MSDS. In fact, MSDSs will probably go beyond the strict requirements of the classification process, because you will probably want to include information that you do not need to put on for classification. For something such as MEK, you may want to say it could be a reproductive poison; you don't have to but you may want to. An MSDS would be the place to do it.

And worker education—what are you going to tell people? You will be communicating all the hazards; you will be telling people about WHMIS. You will be telling them what is meant by a label, what is meant by a symbol, what is meant by a risk phrase and how to interpret an MSDS.

Classification is intrinsic; it is the base of WHMIS. Without it you don't have WHMIS.

Dennis Purton

Why is the classification not requested or required on an MSDS?

Geoff Granville

The classification is intrinsically part of an MSDS. You can't write a WHMIS-compatible MSDS without having done your classification.

Dennis Purton

But why isn't it a requirement? It's a standard item; you've told us all to do it. Then you say just use the data to carry on with your other information. Why not pass the classification along?

Geoff Granville

Some companies will, but we don't insist upon it. Remember, people will see the labels before they will see an MSDS. The label is a reflection of the classification.

Sandra Glasbeek
Ontario Ministry of Labour

I'm one of the people responsible for the legislation implementing WHMIS. Although it is not be an actual requirement for the

Sandra Glasbeek *continued*

classification to be stated on the MSDS, it is certainly part of the drive in the information that you put on the MSDS. In addition to that, the classification must be on the label. You have the hazard symbol relating to the class or classes into which the mixture falls. The worker education will teach people to recognize the meaning behind those symbols and the precautions that need to be taken. The label on which the classification must be presented is intended as the first warning device to workers of a hazardous material and the properties of the material about which they must know and the precautions to take.

The first part of the warning system of the whole right-to-know system is the label, and the label has the classification directly on it. This applies whether it is a supplier label or a workplace label. A workplace label has to give information for the safe handling of the product. The best way of giving that information is to provide the classification, either by the symbol or in words, plus some preventive measures that need to be taken. The test of a workplace label is does it alert the worker to the hazards of that material? The only way you can do that is by presenting the classification. The whole system is devised so that the label is the first warning alert that tells people what the classification is and what the related hazards are. They are then told to go to the Material Safety Data Sheet to get more and better information on the hazard and the precautions. Classification is the driving system because it decides whether a product is within WHMIS or not; but it also provides the first warning alert to the worker of the precautions that need to be taken.

Tom Peiper
Alberta Community and Occupational Health

I fully agree with Sandra Glasbeek. Classification is just one part of WHMIS. It is the backbone; it classifies materials according to hazard groups. That's only one part of the system. The rest deals with labels, the MSDS and worker education programs. Each one has a definite purpose.

Classification of Imports from USA and EEC

Presenter: David Gaylor
Chairman: Richard Morris

Lillian Vine

There appear to be many unanswered questions on WHMIS. The Centre has been asked to get people together in the early fall, who could profit from speaking with one another, seeing where they're at, what they're doing and how. We had thought that September might be too late but were told that much would still need to be done in early fall. How many of you would be interested? Some of you said "too late" but others put up their hands. I expect the Centre will follow through; you can expect that workshop in late September.

Our next speaker is David Gaylor. He has a Degree in Chemical Engineering from the University of Waterloo and a Master's Degree of Engineering, Industrial Hygiene and Safety Engineering from the University of Toronto. He has been working for C-I-L for some time. Between 1976 and 1980, he provided primarily environmental engineering services to the C-I-L mercury cell chloralkali plants. Since 1981, he has been part of C-I-L's Occupational Health group and is the Manager of Occupational Hygiene. He manages C-I-L's Regional Occupational Hygiene Program (seven Regional Hygienists servicing 6,000 employees in 100-plus locations across the country). David will discuss the Classification of Imports from the USA and EEC. The Chairman for this session is Richard Morris.

David Gaylor

Why would anyone be concerned about the classification of imports from the US and the European Economic Community? The answer lies in the definition of supplier under the Hazardous Products Act as "any person who manufactures, processes or packages a controlled product, or who, in the course of business, imports or sells controlled products." That is very significant, because importers, whether they are using the product in their own plant, re-formulating it, or selling it to somebody else just as it is, are considered a supplier. Under the Hazardous Products Act all the provisions that apply to a supplier apply to importers. In other words, the classification process will have to be gone through, a Material Safety Data Sheet will have to be produced as will a supplier label. An understanding of the classifications used in Europe and in the US will help re-classify the products that are coming to you as an importer. (Reference paper: Appendix 2—Classification of Imports from USA, EEC)

This presentation is designed to highlight some of the differences between the classification systems used in Europe under the

David Gaylor *continued*

European Economic Community directive for labelling products and in the US under the OSHA Hazard Communication Standard. We will be talking about the differences in the systems, that is: where there are fewer criteria, more criteria, or different types of criteria that fall into a similar classification; different class types; different specified test methods; different defined hazard symbols; and different ways of classifying mixtures or preparations, as they are called in Europe. Although there are many similarities between the classifications used in Europe, the US and WHMIS, there are also many differences. These have to be considered very carefully when you are re-classifying your product.

Let's start by comparing WHMIS to the US OSHA Hazard Communication Standard, with which imports from the USA will likely comply. The OSHA Hazard Communication Standard is similar in scope to the WHMIS system. It deals with classification, label content, MSDS content, and worker education. It has physical and health hazard definitions that are similar to, but a little different from, what we have in Canada under WHMIS.

The biggest difference is that it is very much a performance standard. Before I prepared this talk, I thought it would be wise to contact our sister company in the US which should be very familiar with the OSHA Hazard Communication Standard. I asked their toxicologist the difference between WHMIS and the OSHA Hazard Communication Standard. He told me that the systems used in Europe and WHMIS are much more specification-oriented and the USA one is more performance-oriented. That means that anything on their Material Safety Data Sheets or on their labels likely has one more review process than ours. All of their MSDSs and labels have to go through the law office first. Because it is a performance standard and because there is more flexibility for what is stated on the label and the Material Safety Data Sheet and because of the legal environment that exists in the US, they are more concerned about liability; so they get their lawyers involved. We hope we don't have to do that here.

Suggested references are given, perhaps a little less than the documentation that Bob provided you with this morning. You have to take into account any relevant scientific reference and the OSHA standard gives references to find that information.

Now to compare the United States OSHA Hazard Communication Standard with WHMIS. As far as labelling is concerned, the content of labels mandated in the US is much less demanding than here. The only guide in the US for use of risk phrases on the labels comes from the American National Standards Institute's standard on precautionary labelling. This standard has existed for a long time

David Gaylor *continued*

but has been updated this year. There you'll find some suggested risk phrases and some suggestions on hazard symbols. Only one of the hazard symbols is mandated by the ANSI standard. In fact, most of the time, the use of hazards symbols is discouraged. OSHA doesn't require that hazard symbols be used at all; ANSI discourages their use for many classifications. This is one of the major differences between OSHA and WHMIS.

I would like to examine the differences in more detail by looking at the criteria themselves. The first difference we run across is the acute lethality classification. In the US the acute lethality defined LC_{50} is much different from Canada's WHMIS. That's because the WHMIS-defined LC_{50} was chosen to match the Transportation of Dangerous Goods Act. You'll find the same thing in Europe; the LC_{50}s are a little different there, but they don't match their Transportation of Dangerous Goods specified LC_{50}s. WHMIS is the only system of the three that matched its transportation regulations.

In the US, there are no specific criteria for chronic effects, reproductive effects, or teratogenicity. But there is a very important category called "target organ effects" where all types of chronic effects, any reproductive effects, and certainly teratogenicity would be considered. For carcinogenicity, they have adopted one of the same lists that we use, IARC, but they also add the National Toxicology Program list and the OSHA carcinogen list. There is a possibility that you could have materials in the US that were classified as carcinogens by NTP but when they cross the border, they are not carcinogens under WHMIS.

Mutagens are not classified, nor are biohazardous infectious materials or dangerously reactive materials. Mutagens may be included because the reproductive system would be a target organ, and any information that is relevant for mutagenicity would probably show up there. You also may have an addition to our classification criteria. Ames test data, which is a mutagenicity test result for bacteria, are very often included on US data sheets. It will not likely show up on WHMIS data sheets because the WHMIS mutagenicity criteria regard only in vivo tests on animals.

There are additional hazard information requirements. For example, for carcinogenicity under the US OSHA Hazard Communication Standard, you have to specify any positive animal study of statistical significance or any human evidence. So some things which wouldn't be on the NTP list may show up as carcinogens on OSHA data sheets simply because there has been a positive animal study. US suppliers are typically more concerned about liability, so add more information to the data sheet.

David Gaylor *continued*

Perhaps a good example of this is polyethylene. Polyethylene and many other similar materials have been tested in subcutaneous tests for carcinogenicity. Some of the materials have been positive—polyethylene was one. Nobody seriously considers that to be positive evidence of carcinogenicity for the ways in which polyethylene is used, but you may see that statement on US data sheets because of the worry about liability.

With target organ effects, any positive animal study of statistical significance will be stated. Also things like lung irritants and pneumoconiosis-causing dusts such as silica, are easily classified by examining the lung as a target organ system under the OSHA standard. Under WHMIS there is no specific reference to lung irritants or lung-damaging diseases outside of respiratory sensitization.

OSHA specifies very few test methods. For irritants, Richard gave a much more specific presentation and outlined what kind of tests you might find for irritants in the US. They are based on Draize or modified-Draize tests.

Another significant difference is that OSHA's acute lethality inhalation test criteria are 1 hour and not 4 hours as they are in the OECD test specified by WHMIS.

Additional classes: OSHA includes explosives which are not regulated in WHMIS since they are covered under the Explosives Act.

Classification of mixtures in the US is very similar to the handling of mixtures in Canada under WHMIS. The 1% and 0.1% rules are very similar. The difference is that 0.1% applies for carcinogens only under OSHA. Under WHMIS, respiratory sensitizers, mutagens, teratogens and carcinogens are included in a 0.1% cut-off. Another difference is that OSHA goes beyond what WHMIS implies; it specifically says the cut-off percentages could be less if you know that the component which is at 0.1% or 1% could be released and exceed the OSHA permissible exposure limit or cause a health hazard when it is released.

One of the very important differences that the OSHA Hazard Communication Standard outlines is to definitely state you have to document your hazard evaluation procedure. When it is challenged, you have a document to back up what you've said. That's very much implied by WHMIS, and we have been emphasizing that you justify your statements or professional judgments used to classify your materials, but it is actually mandated in the US in the regulations.

David Gaylor *continued*

Hazard symbols are not required by OSHA at all. They are not mandated, and it is entirely optional to use a hazard symbol or not. The American National Standard Institute, which is not mandated by OSHA, recommends only one symbol, and that is for the highly toxic class. When we get into the direct comparisons, you will be able to see what relationship highly toxic has with our very toxic and toxic. There is an appendix to the ANSI standard which reviews the process of evaluating hazard symbols and makes several recommendations. Basically, they discourage the use of any hazard symbol that people don't readily recognize. The approach in WHMIS is to train people to recognize the specified hazard symbols.

Now we move on to imports from the European Economic Community. First of all, there are no MSDS requirements in the EEC regulations but each of the European countries has its own requirements for MSDS. For example, the UK has its own Occupational Health and Safety Act regulations which requires an MSDS, but the actual content is not specified as it is in Canada and in the US. The major purpose of the EEC directive is for product labelling. Many risk phrases, hazards symbols and safety advice phrases are defined and used on product labels. There is a professional judgment component in applying the criteria and risk phrases. On the other hand, there are a great number of compounds for which the hazard symbols, risk phrases, and safety advice phrases are already mandated. There is an annex to the directive with a list of compounds. The EEC directive is about 20 years ahead of us and it has been updated significantly in the last few years. Perhaps that's why they actually have a list and we don't.

A proposed preparations regulation will be mandating MSDSs; I understand it has a very complex way, compared to WHMIS, of classifying preparations. It is similar to two sets of existing preparations regulations for paints, solvents, printing inks, and the like.

The first item we find in examining criteria differences between the EEC directive and WHMIS is the flash point ranges for flammability. The EEC has three classes of flammability—highly flammable, very flammable and flammable. Under acute lethality, the LD_{50} and LC_{50} ranges don't match ours. They have also added the risk phrase that recognizes there may be other serious acute effects that are caused in test animals when doing LD_{50} or LC_{50} tests, or prior to the stage where you get to those kinds of doses. That should be communicated and they have provided for stating those. That's not specifically required under WHMIS at all. There are chronic effects specified doses, which are different

David Gaylor *continued*

from ours. There are also carcinogenicity guidelines that use IARC definitions, but not the IARC lists. So you could have similarities in classifications for carcinogenicity but there is provision for judgment. Their definition of irritant also is different because it specifically includes respiratory irritants.

Compressed gases are not classified in EEC, although they are covered under transportation regulations. Reproductive toxicity isn't specifically outlined in the criteria, but certainly would be considered as a chronic toxic effect; it would be communicated in the safety advice phrases and the risk phrases that accompany materials that have reproductive toxicity risks. Biohazardous infectious materials are not included in the EEC directive on labelling, only in the transportation regulations.

Additional classifications used in Europe are explosives and a class called "harmful." In Europe the classes are very toxic, toxic and harmful. "Harmful" affects several of the WHMIS classifications. Some overlaps are chronic toxic effects, mutagenicity, carcinogenicity, acute lethality, and respiratory tract sensitization criteria.

Hazard symbols are mandated in the EEC and they've gone a little further than we have by specifying the colour and the size of the hazard symbols used on a label. There are hazard symbols for an irritant class, a harmful class and, of course, the explosive class, which are different from WHMIS hazard symbols. The other hazard symbols that are defined by the EEC directive are very similar to those used in WHMIS.

The classification of mixtures will be separately regulated and is already separately regulated for very specific preparations like paints, varnishes, printing inks, solvents, etc. In those regulations and in the proposed regulations, there is an assignment of hazard indices for a number of solvents. The sums of the products of the per cent weight in those indices are used to class them as very toxic, toxic or harmful. That's a very different approach from WHMIS which specifies a per cent cut-off.

There are also concentration limits specified which are used to classify corrosives, irritants, non-lethal irreversible acute effects, long term effects, carcinogens, mutagens and teratogens. The concentration limits rules are very different, especially those dealing with corrosives and irritants. Often the per cent cut-off specified for those kinds of materials is 5%, 10%, or even more. That is very different from our 1%. Even respiratory sensitizers can be as high as that; certainly they are more than 0.1%.

David Gaylor *continued*

I would like to go through each of the WHMIS classifications separately and compare hazard symbols and classification criteria for EEC, OSHA AND WHMIS.

First, there is compressed gas, Class A. In Europe, it is not classified; the OSHA compressed gas criteria are very similar to those used in WHMIS.

In WHMIS, flammable concentration ranges are specified under the flammable gas classification. These are the same as those used in the US OSHA Hazard Communication Standard. An important difference in Europe is that there are no specific criteria used to define a flammable concentration range. Under WHMIS, a spread of 12% or 13% is needed between the lower and higher flammable limit before it is considered a flammable gas. No such concentration differences are specified in Europe.

The criteria used in the US for flammable liquids are the same as those used in WHMIS, i.e. a flash point less than 100°F. The flammability ranges in Europe are different, with flash points less than 0°C and also between 0°C and 21°C. Those both span the flammable liquid classification in WHMIS. The US and WHMIS systems have the same classification for combustible liquids; that is, a flash point between 100°F and 200°F. But flammable liquid in the EEC has a flash point of between 21°C and 55°C, so that starts below and goes beyond the WHMIS and OSHA criteria. There's an overlap, but it's not the same.

Flammable solids are very similarly described in all three jurisdictions. Flammable aerosols are covered under a separate European directive. The OSHA criteria are very much the same as the WHMIS criteria. The EEC directive that includes aerosols is handled differently.

Reactive flammable materials are included under flammable solids in the US; the definition and risk phrases applied in Europe are very similar to those used in Canada.

Definitions of oxidizing materials are very similar in all jurisdictions. In the US, peroxides have a separate class, but are still considered oxidizers.

In the classification for acute lethality, we begin to see some of the differences in LD_{50}s and LC_{50}s. OSHA and WHMIS have the same LD_{50} oral and dermal specifications, but differ as far as LC_{50} criteria are concerned. Europe doesn't match either one; the oral and dermal LD_{50} ranges are different. For example, an oral LD_{50} is less than 25 mg/kg in the very toxic classification

David Gaylor *continued*

in Europe, and the LD_{50} range specified in WHMIS is less than 50 mg/kg for the same very toxic classification.

In Subdivision B, Toxic, the ranges are different under acute lethality. OSHA matches ours in the toxic class for oral and dermal but inhalation is different. The problem in getting products from Europe is that the oral and dermal LD_{50}s start below our very toxic range and go somewhat into the toxic range. The ranges are very similar but different enough that you wouldn't be able to trust that classification. You would have to actually know the LD_{50} and LC_{50} to re-classify. Then, in Europe there is the harmful class, which starts in the WHMIS toxic range and goes beyond it.

All chronic toxic effects are included as target organ effects in OSHA. You examine each target organ system, evaluate animal studies and human data that might relate to any adverse target organ health effects and communicate those. Under WHMIS, very specific animal dose criteria are used, although we learned today that you certainly wouldn't exclude human evidence such as silica exposure causing pneumoconiosis in humans. Just because it hasn't been tested in an animal doesn't mean you wouldn't consider classifying it as Class D, Division 2, because it has serious chronic toxic effects. In Europe, there are no specific chronic toxic effects doses listed, except that they say any functional disturbance or morphological change at doses that are much less than the specified harmful doses.

The chronic effect doses that are specified under the European harmful class are similar to, but not the same as, our Subdivision B, Toxic chronic effects class in WHMIS.

Teratogenicity and embryotoxicity have very similar definitions in Europe and in Canada under WHMIS except that under the EEC directive, depending on the evidence, it could be classified as toxic, very toxic or harmful. In a preparation, that would depend on some specified cut-off concentration. OSHA regards target organ effects and thus these would be examined as part of the reproductive system.

WHMIS and OSHA are very similar in the classification of carcinogenicity. Both use recognized IARC Group 1 and 2 lists of carcinogens; then WHMIS starts to depart. We use the ACGIH list and the US uses the NTP and OSHA lists. In Europe, they use the definitions for IARC Group 1 and 2 for toxic and very toxic and the IARC Group 3 for harmful, but they don't actually specify that if the compound you use is on that list, it is definitely classed that way. There is some judgment involved. You will find that the annex to the directive will specify which class it should be, and it doesn't always match what's in the IARC lists.

David Gaylor *continued*

There are no specific criteria in Europe for reproductive toxicity, although it is considered a serious chronic toxic effect and has risk phrases and safety advice phrases assigned for this type of effect. The hazard symbol would be mandated in their annex list. Again, OSHA examines all evidence for the reproductive target organ system.

Respiratory tract sensitization has the same definition in Europe and in Canada under WHMIS, except that in Europe it is classified as harmful as opposed to very toxic in Canada. In a preparation, the cut-off range is 0.1% in Canada, but is much higher in Europe, possibly up to 10%. OSHA does have a sensitizer class; it includes skin sensitizers with lung sensitizers which are considered in the same way. If you are classifying a preparation or mixture, the cutoff is 1% there and 0.1% here.

Mutagenicity is not classified in the US specifically, but you certainly will see statements about mutagenicity because it is a factor in carcinogenicity evaluation, and therefore you will see animal studies and Ames test results reflecting mutagenicity criteria. The definition for mutagenicity in Europe and under WHMIS is exactly the same, although the classification may vary.

Under mutagenicity, Subdivision B, Toxic classification, the only difference you will find between the European directive and WHMIS is that theirs will be classed as harmful whereas here you would get the toxic class designation.

Skin or eye irritation was reviewed very thoroughly this morning. The only difference between the European regulations and WHMIS is that, although the definitions are the same, the skin and eye irritants in Europe would be called "harmful" and here they would be called "toxic."

With skin sensitization we have a match.

WHMIS is the only one to classify biohazardous infectious materials.

This morning, we heard that the classification criteria for corrosives under WHMIS specifically states corrosive to metals, corrosive to skin or corrosive gases. In the US there is a difference because they exclude inanimate objects, so corrosive to metals is not considered in the classification system. The definitions in Europe only refer to skin; yet if you look at their hazard symbol, it is the very same as ours. That is, corrosivity to metal is represented on the symbol.

David Gaylor *continued*

The classification for explosives is not covered under WHMIS because we have a separate act to cover that, but it is in the US and EEC.

Dangerously Reactive Materials are not classified in the US, but in Europe there are specific risk phrases and safety advice phrases for some of the aspects of dangerously reactive materials that are specified in WHMIS regulations. They don't have a hazard symbol as we do.

So, we have a bit of a problem. If you're a supplier who imports materials, and the WHMIS classification is not done by your supplier who is out of the country, you have to re-classify. You can see there are enough differences that it is like starting from scratch in many cases. A good strategy would be to have your parent or your supplier in the US or Europe classify the product based on the WHMIS criteria, which would save you some effort. Chances are you are going to have to do a lot of that yourself.

In conclusion, very few classifications are directly equivalent, although some fall completely within the WHMIS criteria. That makes it easier. In any case, if you're left with the job of classifying materials that you import from the US or from Europe, you will have to obtain sufficient formulation information to classify them. You will have to obtain Material Safety Data Sheets for them to complete your own. If you are importing from the US, you may find it helpful to get a copy of their documented justification for their classification. This will make it easy for you to re-classify under the WHMIS rules because all the raw data will be there. It may be more difficult with products from Europe because the content of their MSDSs are not specified as they are in North America. You may find that MSDSs coming from Europe have a lot less information than ours, so your job might be harder.

Questions

Richard Morris

As you can see, there are some differences for people who are suppliers or importers on this side of the ocean or border. Certainly it is a fair job to see what the similarities and differences are. Are there any questions?

David Whaley
Ministry of Labour

Is there a similar system on the way in Japan?

Geoff Granville

Japan has had a system for many years, but it is not as well developed or exported as the other three groups you are looking at today. As with most things in Japan, there has been very good cooperation between industry and government.

Don Macaulay

You mentioned that there were risk phrases used in the US that were based on ANSI standards. I think I read somewhere, perhaps in CMA literature, that these would also be good phrases to use in Canada. Can anyone confirm that?

David Gaylor

There are no mandated risk phrases in Canada, so the risk phrases that are used in Europe and suggested by the ANSI standard would be very good to use as long as they comply with our classification.

Tom Pieper
Alberta Community and Occupational Health

The WHMIS Steering Committee report has a section that deals with a list of risk phrases that you could also use. I think most of them still apply and may be used in the core material.

Richard Morris

Those risk phrases came from the EEC list, and it obviously was not intended to put these into the regulations. Some people are aware that there is a WHMIS core material draft which elaborates on how to carry out requirements under WHMIS and it does go into such details as the choice of risk phrases.

Lillian Vine

I want to thank you all very much for your participation, for sharing your expertise, your experience and especially your questions and your doubts, because they are also very important. This is not a subject about which everybody knows everything. Nobody can give you all the answers. It's terrific that people are sharing; and together you will find the answers and get the system working.

I want to thank the people on our panel—David Gaylor, Bob Whiting, Richard Morris, Geoff Granville and Marc Baril. I also want to thank Peter Robson in absentia. I particularly want to thank Geoff and Peter for requesting these workshops and for working very hard with us on the planning of them and for ingeniously developing materials 1 and 2.

Appendix 1
WHMIS Classification of Manufactured Articles

G P Robson
Du Pont Canada Inc

1. Manufactured articles are exempted completely from the scope of the Controlled Products Regulations (CPR) and Model Provincial Workplace Regulations (Model OSH) for WHMIS.

2. A manufactured article is defined in the Federal Hazardous Products Act (HPA) Section 11(1) and must meet all three conditions below:

    i) It is formed to a specific shape or design during manufacture;

    ii) its intended use when in that form depends in whole or in part on its shape or design; and

    iii) under normal conditions of use it will not release or otherwise cause a person to be exposed to a controlled product.

3. The overall intent of this definition is to ensure that articles which contain controlled products in such a way that the controlled product is bound within the article and is not released under normal, expected conditions of use, are exempted from the scope of WHMIS. Without this exemption such articles containing controlled products at or above the relevant cut-off concentration, would be classified as controlled products.

4. Any product, be it a manufactured article or not, which is not classified as a WHMIS controlled product based on the properties of its components, is exempted completely for WHMIS requirements.

5. The following interpretations of the three conditions in HPA 11(1) are recommended:

    i) "Specific shape or design" refers to the geometric shape or outline and not the materials of which it is made.

    ii) "Intended use depends in whole or in part on shape or design" refers to the essential nature of the shape or design in the intended use.

Item	Intended use	Is Shape/ Design Essential to Use
Metal Pipe	Conveying fluids	Yes
Metal ingot	Melting to manufacture metal pipe	No
Polyethylene film	Garbage bag manufacture	Yes
Polyethylene resin	Melting to make polyethylene film	No

iii) "Normal Conditions of Use" refers to normally expected conditions for the article in its intended use. Clearly this implies some assumption of knowledge on the part of the article supplier regarding the uses to which customers subject the article. This would exclude abuse of the article, for example in accidental or deliberate burning or destruction. The WHMIS Core Material Manual includes the policy that releases of a controlled product which may occur during installation or maintenance of an article are excluded from the scope of "normal conditions of use".

iv) "Release of, or exposure to, a controlled product from an article" refers to only those controlled products present in the manufactured article at concentrations which caused the article to be classified as a controlled product in the first case. It does not include controlled products which are decomposition products, byproducts, reaction products, etc. formed and released during use of the product.

It also does not include trace releases of controlled products which present no health hazard under use conditions.

Note: When an article releases controlled product(s) and is not exempt under the manufactured article exemption, the WHMIS hazard information and ingredient disclosure requirements apply only to the released product(s) and do not apply to controlled products which are bound in the article and are not released.

Identification of hazardous decomposition products and byproducts should be provided on MSDS but toxicological information is not required for releases that are not ingredients of the product.

6. Examples

   i) Stainless steel piping is a manufactured article because it does not release metal during normal use for conveying fluids. Metal release from cutting or grinding during installation or repair is not considered to be "normal conditions of use".

   ii) A lead ingot is not a manufactured article because its normal use is to be melted to form other shapes and it releases lead during melting. Lead is a controlled product. A lead counterweight designed for a hoist is a manufactured article because no controlled product release occurs during normal use.

   iii) A cylinder containing Fluorocarbon 22 (a refrigerant) is a controlled product because it contains a compressed gas. An industrial air-conditioning unit containing F-22 is a manufactured article, since the compressed gas system is just one of several components and no significant release of F-22 occurs.

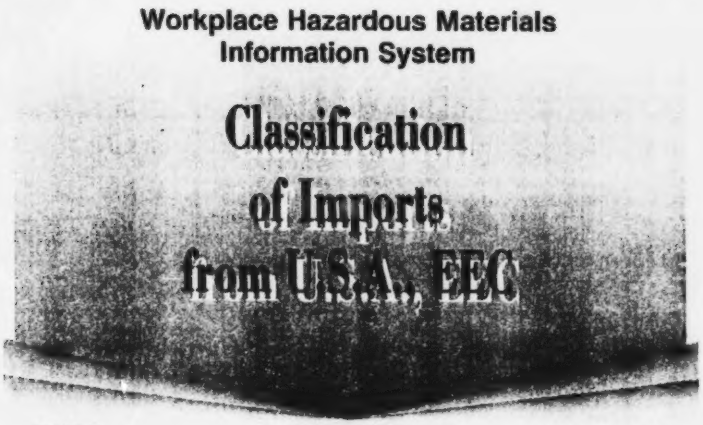
   iv) A sheet of asbestos filled gasket material intended to be cut and shaped to fit into other products is a controlled product since release of asbestos fibres occurs. A laboratory oven fitted with such asbestos filled gaskets is a manufactured article.

   v) A styrene-polyester resin for use in corrosion resistant tank construction is a controlled product because it contains more than 1% styrene monomer.

      An industrial tank made from this resin has a distinct odour of styrene. The free styrene content is less than 0.1% and therefore it is a manufactured article regardless of the temporary low level release of styrene.

Appendix 2

A332.26 8803 P/E ☐ C/R ☐

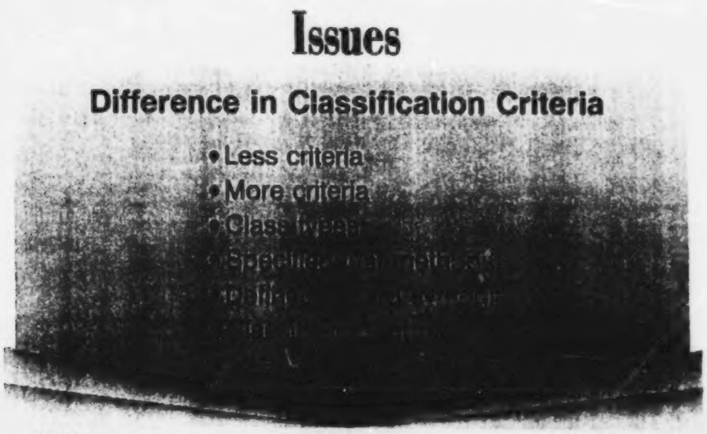


Workplace Hazardous Materials
Information System

Classification
# of Imports
from U.S.A., EEC

JCH/jdh 08-Feb-88 A·V·E·N·U

A332.27 8803 P/E ☐ C/R ☐



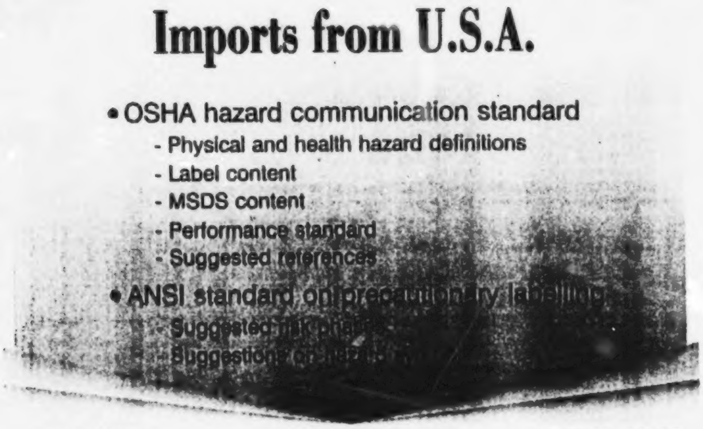
Issues

Difference in Classification Criteria

- Less criteria
- More criteria
- Class types
- Specific [illegible]
- Defin[illegible]
- [illegible]

JCH/cv 15-Feb-88 A·V·E·N·U

A332.28 8803 P/E ☐ C/R ☐

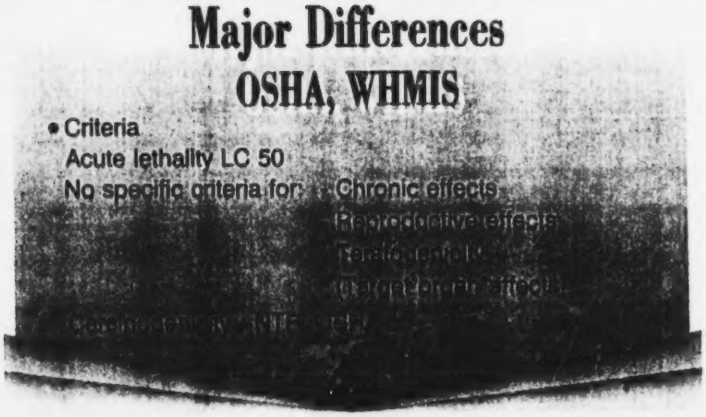


Imports from U.S.A.

- OSHA hazard communication standard
  - Physical and health hazard definitions
  - Label content
  - MSDS content
  - Performance standard
  - Suggested references
- ANSI standard on precautionary labelling
  - Suggested risk phrases
  - Suggestions on [illegible]

JCH/cj/jdh/cv 15-Feb-88 A·V·E·N·U

A332.29 8803 P/E ☐ C/R ☐



Major Differences
OSHA, WHMIS

- Criteria

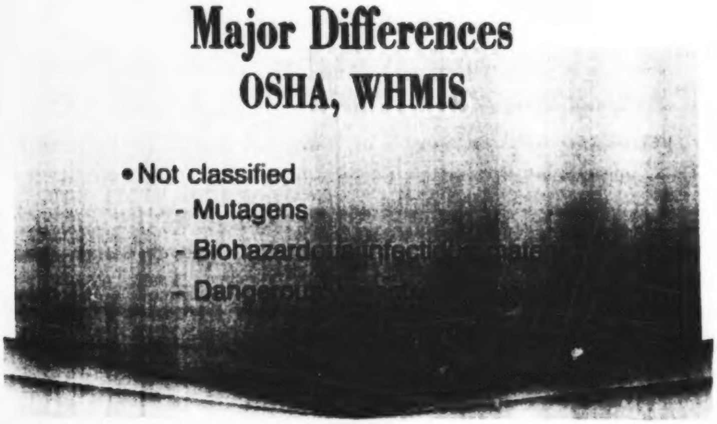
Acute lethality LC 50

No specific criteria for: Chronic effects
Reproductive effects
[illegible]
[illegible]

[illegible]

CJ/jdh/cv 15-Feb-88 A·V·E·N·U

B357.02 8878 P/E☐ C/R☐

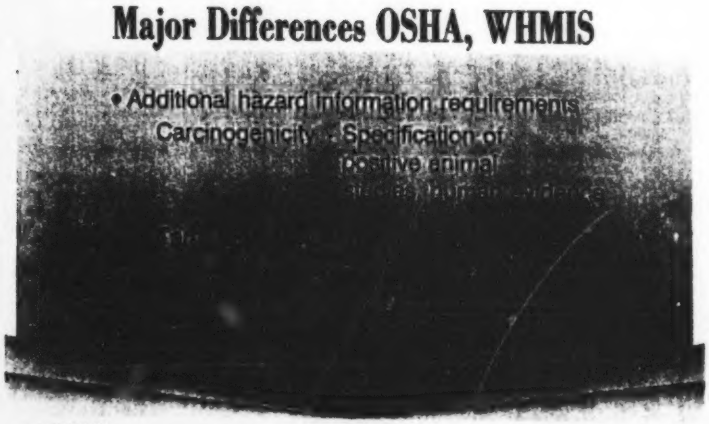


Major Differences
OSHA, WHMIS

- Not classified
  - Mutagens
  - Biohazardous infectious material
  - Dangerous [illegible]

JCH 14-Mar-88 A·V·E·N·U

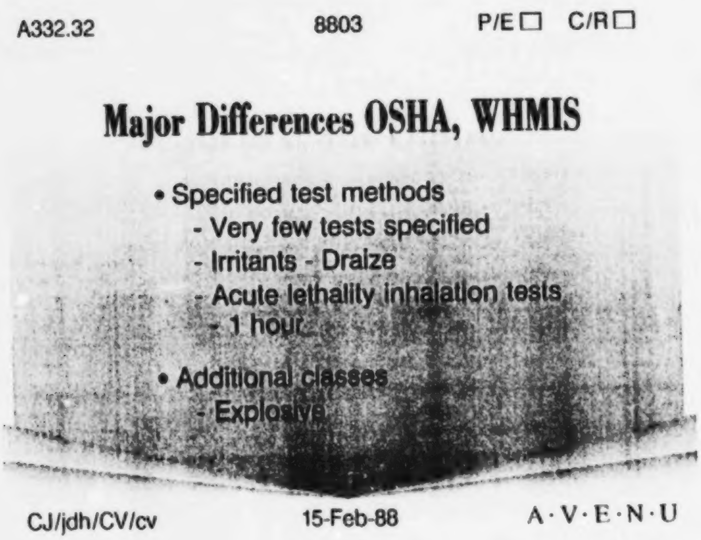
A332.31 8803 P/E☐ C/R☐



Major Differences OSHA, WHMIS

- Additional hazard information requirements
  Carcinogenicity - Specification of
  positive animal
  studies, human evidence

cvCJ/jdh 15-Feb-88 A·V·E·N·U

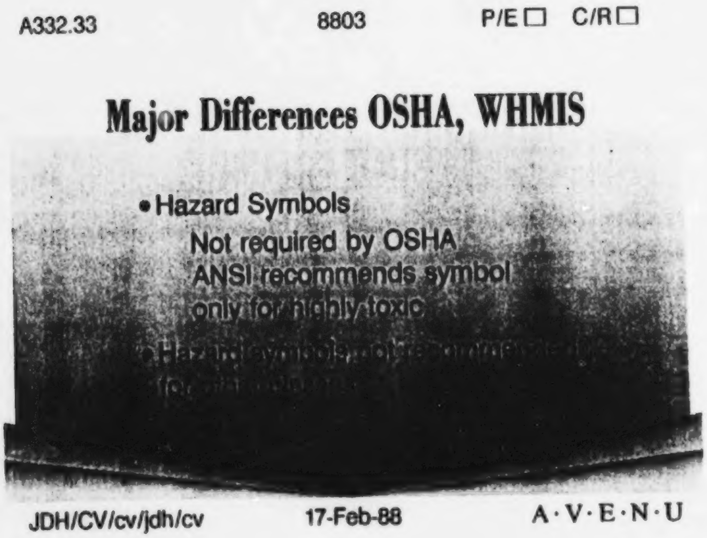


A332.32 8803 P/E ☐ C/R ☐

Major Differences OSHA, WHMIS

- Specified test methods
  - Very few tests specified
  - Irritants - Draize
  - Acute lethality inhalation tests
    - 1 hour
- Additional classes
  - Explosive

CJ/jdh/CV/cv 15-Feb-88 A·V·E·N·U

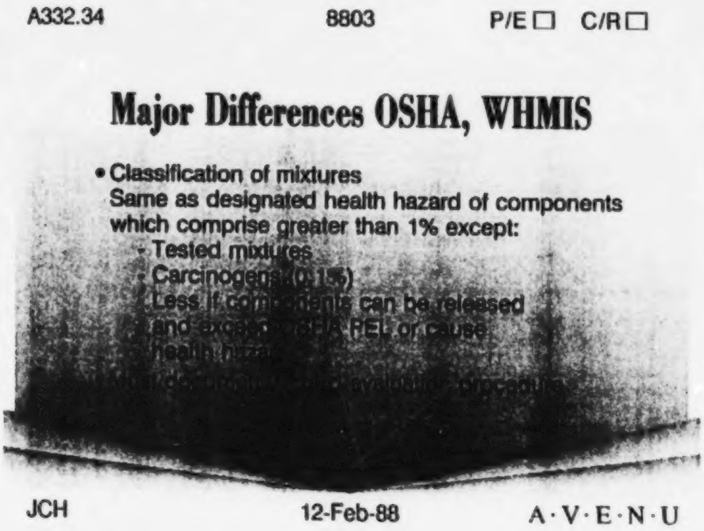


A332.33 8803 P/E ☐ C/R ☐

Major Differences OSHA, WHMIS

- Hazard Symbols
  Not required by OSHA
  ANSI recommends symbol
  only for highly toxic
- Hazard symbols not recommended [illegible]
  [illegible]

JDH/CV/cv/jdh/cv 17-Feb-88 A·V·E·N·U

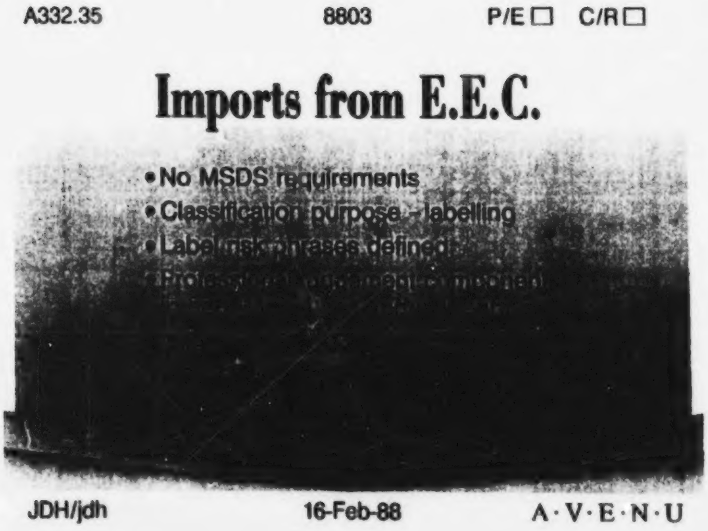


A332.34 8803 P/E ☐ C/R ☐

Major Differences OSHA, WHMIS

- Classification of mixtures
  Same as designated health hazard of components which comprise greater than 1% except:
  - Tested mixtures
  - Carcinogens (0.1%)
  - Less if components can be released and exceed OSHA PEL or cause health hazard
- [illegible] evaluation procedure

JCH 12-Feb-88 A·V·E·N·U



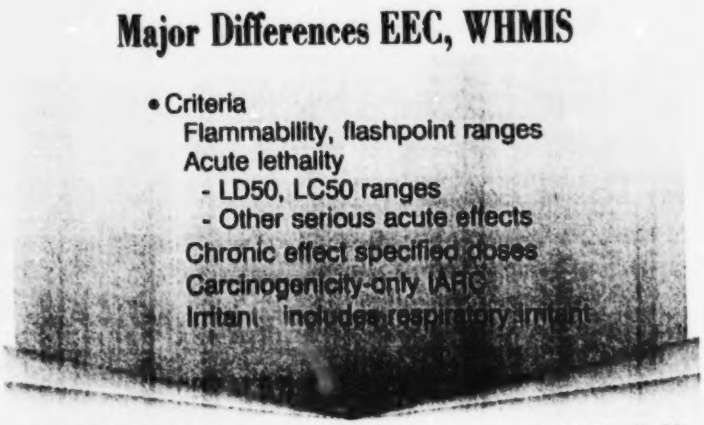
A332.35 8803 P/E ☐ C/R ☐

Imports from E.E.C.

- No MSDS requirements
- Classification purpose - labelling
- Label risk phrases defined
- [illegible]

JDH/jdh 16-Feb-88 A·V·E·N·U

A332.36 8803 P/E☐ C/R☐

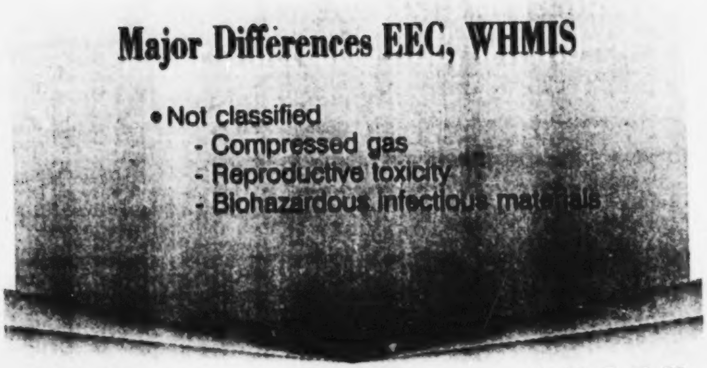


Major Differences EEC, WHMIS

- Criteria
  Flammability, flashpoint ranges
  Acute lethality
    - LD50, LC50 ranges
    - Other serious acute effects
  Chronic effect specified doses
  Carcinogenicity-only IARC
  Irritant includes respiratory irritant

JCH/jdh/cv/jdh 16-Feb-88 A·V·E·N·U

A332 37 8803 P/E☐ C/R☐

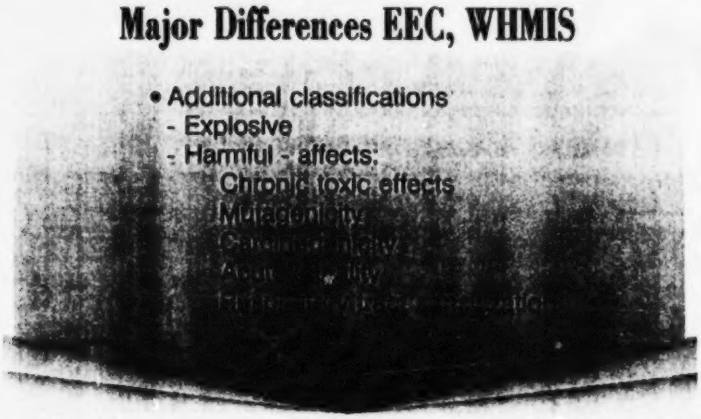


Major Differences EEC, WHMIS

- Not classified
  - Compressed gas
  - Reproductive toxicity
  - Biohazardous infectious materials

JCH/JDH 12-Feb-88 A·V·E·N·U

A332.38 8803 P/E ☐ C/R ☐

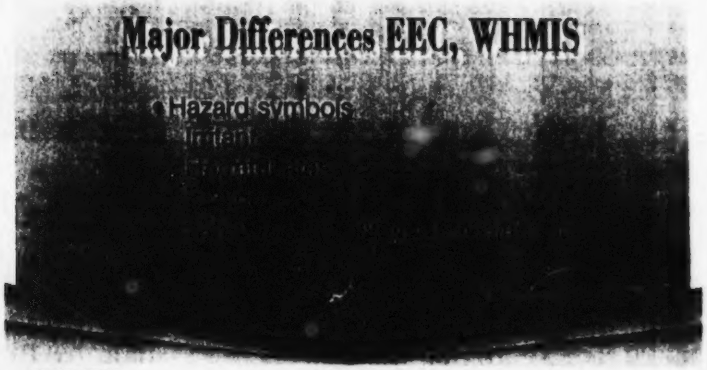


Major Differences EEC, WHMIS

- Additional classifications
  - Explosive
  - Harmful - affects:
    - Chronic toxic effects
    - Mutagenicity
    - Carcinogenicity
    - [illegible]
    - [illegible]

JCH/JDH/cv 15-Feb-88 A·V·E·N·U

A332.39 8803 P/E ☐ C/R ☐



Major Differences EEC, WHMIS

- Hazard symbols
  - Irritant
  - [illegible]

JCH/JDH 12-Feb-88 A·V·E·N·U

A332.40 8803 P/E☐ C/R☐

Major Differences EEC, WHMIS

- Classification of Mixtures
  Separate regulation
  Assignment of hazard indices
  Sums of products of % weight and indices used to class as:
  - Very toxic
  - Toxic
  - Harmful

JCH/jdh 12-Feb-88 A·V·E·N·U

A332.41 8803 P/E☐ C/R☐

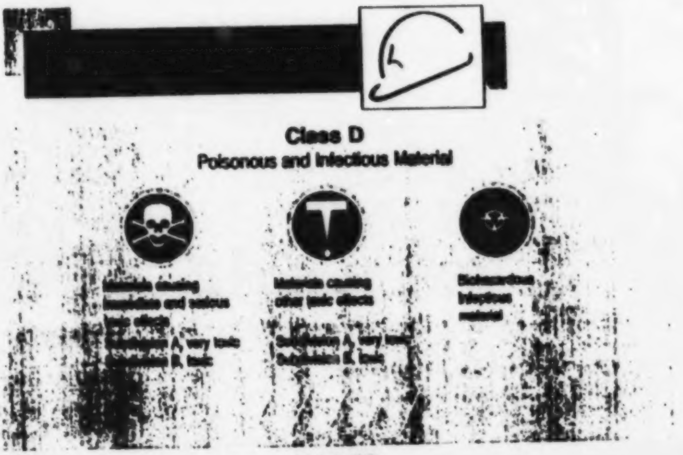
Major Differences EEC, WHMIS

- Classification of Mixtures
  Concentration limits specified used to classify:
  - Corrosives
  - Irritants
  - Non-lethal irreversible acute effects
  - Long term effects
  - Carcinogens, mutagens, teratogens

  Corrosives, irritants, combinations : additive

JCH/jdh 12-Feb-88 A·V·E·N·U

A332.43 8803 ➡



Class D
Poisonous and Infectious Material

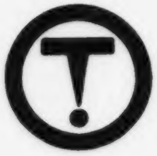
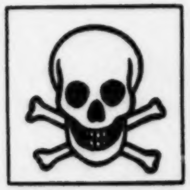
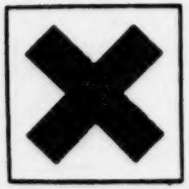
Materials causing immediate and serious toxic effects
Subdivision A, very toxic
Subdivision B, toxic

Materials causing other toxic effects
Subdivision A, very toxic
Subdivision B, toxic

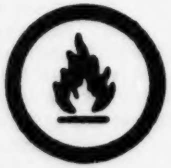
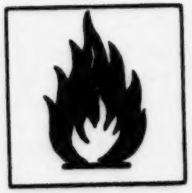
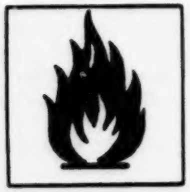
Biohazardous infectious material

JDH 17-feb-88

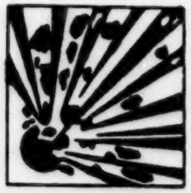
CLASSIFICATION: TERATOGENICITY, EMBRYOTOXICITY

CPR SECTION 53	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T  Xn 
CRITERIA	- SUBDIVISION A, VERY TOXIC - SHOWN TO CAUSE: - DEATH - MALFORMATION - PERMANENT METABOLIC OR PHYSIOLOGICAL DYSFUNCTION - GROWTH RETARDATION - PSYCHOLOGICAL OR BEHAVIORAL ALTERATION DURING PREGNANCY, AT BIRTH, OR IN POSTNATAL PERIOD	- NO CRITERIA SPECIFIED - WOULD BE INCLUDED IN REPRODUCTIVE TOXIN, TARGET ORGAN CATEGORIZATION	- TOXIC, VERY TOXIC CATEGORY 1 (R47) - KNOWN TO BE TERATOGENIC IN MAN - EVIDENCE OF EXPOSURE TO SUBSTANCE AND SUBSEQUENT NON-HERITABLE BIRTH DEFECTS IN OFFSPRING - HARMFUL CATEGORY 2 (R47) - SHOULD BE REGARDED AS IF THEY ARE TERATOGENIC IN MAN

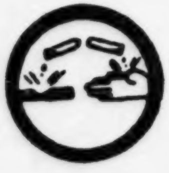
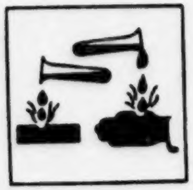
CLASSIFICATION: FLAMMAPLE LIQUID

CPR SECTION 37	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS B, DIVISION 2	- FLAME SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	F  F+ 
CRITERIA	- FLASHPOINT $< 37.8^\circ C$ ($100^\circ F$)	- SAME AS WHMIS CRITERIA - MIXTURES HAVING COMPONENTS WITH FLASHPOINTS $\geq 100^\circ F$ AND COMPRISING $\geq 99\%$ OF THE TOTAL VOLUME WILL NOT BE CLASSED AS FLAMMABLE LIQUIDS	- EXTREMELY FLAMMABLE FLASHPOINT $< 0^\circ C$ AND INITIAL BOILING POINT $\leq 35^\circ C$ F+, (R12) - HIGHLY FLAMMABLE $0^\circ C \leq$ FLASHPOINT $< 21^\circ C$ F , (R11)

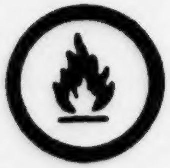
CLASSIFICATION: EXPLOSIVE MATERIAL

CPR SECTION	WHMIS	OSHA	EEC
HAZARD SYMBOL		- EXPLOSIVE HAZARD SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	E 
CRITERIA	- NOT CLASSIFIED - COVERED UNDER FEDERAL EXPLOSIVES ACT	- CHEMICAL THAT CAUSES A SUDDEN ALMOST INSTANTANEOUS RELEASE OF PRESSURE, GAS AND HEAT WHEN SUBJECTED TO SUDDEN SHOCK, PRESSURE OR HIGH TEMPERATURE	- RISK OF EXPLOSION BY SHOCK, FRICTION, FIRE OR OTHER SOURCES OF IGNITION (R2) - EXTREME RISK OF EXPLOSION BY SHOCK, FRICTION, FIRE OR OTHER SOURCES OF IGNITION (R3)

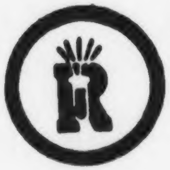
CLASSIFICATION: CORROSIVE MATERIAL

CPR SECTION 65	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS E	- HAND CORROSIVE SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	C 
CRITERIA	A) CORRODES SAE 1020 STEEL OR 7075-T6 NON-CLAD ALUMINUM AT >6.25 MM/YR AT 55°C B) CORROSIVE TO SKIN IN ACCORDANCE WITH OECD 404 C) IN CLASS 8, PART III, TDG D GAS IN DIVISION 4, CLASS 2, PART III, TDG E) POSITIVE EVIDENCE OF VISIBLE NECROSIS OF HUMAN SKIN TISSUE F) MEETS (B) & (E) AND PRESENT AT ≥1% IN MIXTURES	- CAUSES VISIBLE DESTRUCTION OR IRREVERSIBLE ALTERATIONS IN LIVING TISSUE - SPECIFICALLY DOES NOT INCLUDE CORROSIVE ACTION ON INANIMATE SURFACES	- CAUSES SEVERE BURNS (R35) - FULL THICKNESS DESTRUCTION OF SKIN TISSUE OCCURS WITH UP TO THREE MINUTES EXPOSURE - CAUSES BURNS (R34) - FULL THICKNESS DESTRUCTION OF SKIN TISSUE OCCURS WITH UP TO FOUR HOUBS EXPOSURE - NO REFERENCE TO CORROSIVITY TO METALS

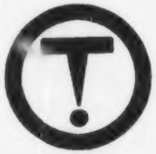
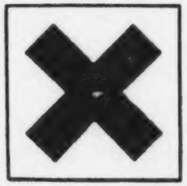
CLASSIFICATION: COMBUSTIBLE LIQUID

CPR SECTION 38	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS B, DIVISION 3		- NO SYMBOL SPECIFIED
CRITERIA	- $37.8^{\circ}C \leq$ FLASHPOINT $< 93.3^{\circ}C$ ($100^{\circ}F$) ($200^{\circ}F$)	- NOT CLASSIFIED	- FLAMMABLE $21^{\circ}C \leq$ FLASHPOINT $< 55^{\circ}C$ (R10) - NOT IF IT CANNOT SUPPORT COMBUSTION AND WILL NOT POSE A FIRE RISK TO HANDLERS

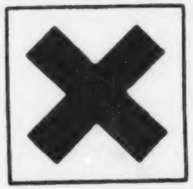
CLASSIFICATION: DANGEROUSLY REACTIVE MATERIAL

CPR SECTION 66	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS F		
CRITERIA	A) UNDERGOES VIGOROUS POLYMERIZATION, DECOMPOSITION OR CONDENSATION B) BECOMES SELF-REACTIVE UNDER CONDITIONS OF SHOCK OR INCREASE IN PRESSURE OR TEMPERATURE C) REACTS VIGOROUSLY WITH WATER TO PRODUCE A GAS WITH AN LC50 $\leq$ 2500 PPM	- NOT CLASSIFIED	- NO DANGEROUSLY REACTIVE CRITERIA - ARE SOME RISK PHRASES DEFINED: - CONTACT WITH WATER LIBERATES TOXIC GAS (R30) - REACTS VIOLENTLY WITH WATER (R14) - CONTACT WITH ACID LIBERATES TOXIC (R31), VERY TOXIC (R32) GAS

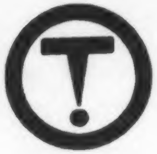
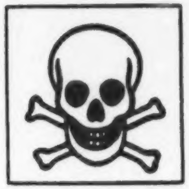
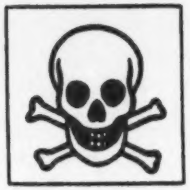
CLASSIFICATION: MUTAGENICITY

CPR SECTION 62	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2		Xn 
CRITERIA	- SUBDIVISION B, TOXIC - EVIDENCE OF MUTAGENICITY IN MAMMALIAN SOMATIC CELLS IN VIVO IS OBTAINED IN SPECIFIED TESTS ASSESSING GENE MUTATION OR CHROMOSOMAL ABERRATION	- NOT CLASSIFIED	HARMFUL - CATEGORY 2 (R46) - A STRONG PRESUMPTION CAN BE MADE THAT HUMAN EXPOSURE MAY RESULT IN HERITABLE GENETIC DAMAGE ON THE BASIS OF APPROPRIATE ANIMAL STUDIES - CATEGORY 3 (R40) - EVIDENCE DOES NOT SATISFACTORILY DEMONSTRATE HERITABLE GENETIC DAMAGE

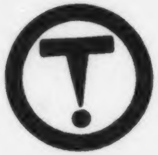
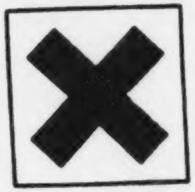
CLASSIFICATION: SKIN OR EYE IRRITATION

CPR SECTION 60	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	XI 
CRITERIA	- SUBDIVISION B, TOXIC SKIN OECD 404 GRADE A) ERYTHEMA FORMATION ≥ 2 EDEMA FORMATION ≥ 2 EYES OECD 405 GRADE B) CORNEAL DAMAGE ≥ 2 IRIS DAMAGE ≥ 1 CONJUNCTIVAL SWELLING, REDNESS ≥ 2.5	- NOT CORROSIVE BUT CAUSES A REVERSIBLE INFLAMMATORY EFFECT AT POINT OF CONTACT ON LIVING TISSUE. - COULD INCLUDE LUNG IRRITANTS SKIN - SCORE OF 5 OR MORE IN 16 CFR 1500.41 (SCORE ADAPTED FROM DRAIZE TEST) EYES - IF SO DETERMINED BY 16 CFR 1500.42 OR OTHER APPROPRIATE TECHNIQUES - MORE SERIOUS RISK OF SKIN AND EYE DAMAGE WOULD BE COVERED IN EVALUATION OF CUTANEOUS AND EYE TARGET ORGAN SYSTEMS	- SKIN (R38) - OECD GRADES - SAME AS WHMIS - SIGNIFICANT INFLAMMATION IS CAUSED AND REMAINS PRESENT FOR MORE THAN 24 HOURS - EYES (R36) - SIGNIFICANT OCULAR LESIONS ARE CAUSED AND REMAIN PRESENT FOR MORE THAN 24 HOURS CORNEAL DAMAGE $2 \leq \text{GRADE} < 3$ IRIS DAMAGE $1 \leq \text{GRADE} < 1.5$ CONJUNCTIVAL REDNESS ≥ 2.5 CONJUNCTIVAL OEDEMA ≥ 2 - SERIOUS DAMAGE TO EYES (R41) SEVERE CORNEAL DAMAGE - GRADE ≥ 3 IRIS LESIONS - GRADE ≥ 1.5 - SERIOUS RESPIRATORY IRRITANT (R37)

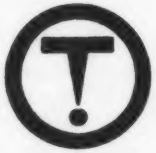
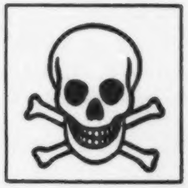
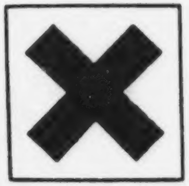
CLASSIFICATION: MUTAGENICITY

CPR SECTION 57	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2		T  T+ 
CRITERIA	- SUBDIVISION A, VERY TOXIC A) EPIDEMIOLOGICAL EVIDENCE OF HERITABLE GENETIC EFFECTS B) EVIDENCE OF MUTAGENICITY IN MAMMALIAN GERM CELLS IN VIVO, IN ACCORDANCE WITH SPECIFIED TEST METHODS	- NOT CLASSIFIED - SIGNIFICANT EVIDENCE OF MUTAGENICITY LIKELY TO BE COVERED IN EVALUATING DATA ON THE REPRODUCTIVE TARGET ORGAN SYSTEM - BACTERIA MUTAGENICITY TESTS (EG AMES TESTS) COULD BE CITED	- TOXIC, VERY TOXIC CATEGORY 1 - SUBSTANCES KNOWN TO BE MUTAGENIC IN MAN, I.E. DEFINITE EVIDENCE OF HERITABLE GENETIC DAMAGE (R46)

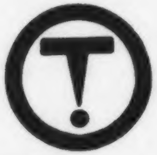
CLASSIFICATION: RESPIRATORY TRACT SENSITIZATION

CPR SECTION 56	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	Xn 
CRITERIA	- SUBDIVISION A, VERY TOXIC - EVIDENCE OF RESPIRATORY TRACT SENSITIZATION FOLLOWING WORKPLACE EXPOSURE	- SENSITIZER - CAUSES A SUBSTANTIAL PORTION OF EXPOSED PEOPLE OR ANIMALS TO DEVELOP AN ALLERGIC REACTION TO NORMAL TISSUE AFTER REPEATED EXPOSURE I.E. SKIN AND LUNG SENSITIZERS ARE COVERED IN THIS CLASSIFICATION	- HARMFUL - CAPABLE OF INDUCING SENSITIZATION REACTION IN HUMANS BY INHALATION AT A GREATER THAN EXPECTED FREQUENCY THAN IN NORMAL POPULATION (R42)

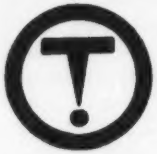
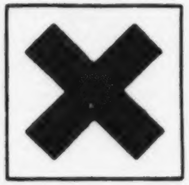
CLASSIFICATION: CARCINOGENICITY

CPR SECTION 54	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T  Xn 
CRITERIA	- SUBDIVISION A, VERY TOXIC A) LISTED IN SECTION A1A, A1B, OR A2 IN ACGIH TLV'S FOR CHEMICAL SUBSTANCES AND PHYSICAL AGENTS IN THE WORK ENVIRONMENT. B) LISTED IN GROUP 1 OR 2 IN THE IARC MONOGRAPHS ON THE EVALUATION OF THE CARCINOGENIC RISK OF CHEMICALS TO HUMANS	- LISTED AS A CARCINOGEN OR POTENTIAL CARCINOGEN BY A) IARC B) NTP, OR C) REGULATED AS CARCINOGEN BY OSHA	- TOXIC, VERY TOXIC CATEGORY 1 (R45) - SUBSTANCES KNOWN TO BE CARCINOGENIC TO MAN (e.g. IARC GROUP 1) CATEGORY 2 (R45) - SUBSTANCES WHICH SHOULD BE REGARDED AS CARCINOGENIC TO MAN ON THE BASIS OF STRONG EVIDENCE(e.g. IARC GROUP 2) - HARMFUL CATEGORY 3 (R40) - SOME EVIDENCE OF CARCINOGENIC POTENTIAL BUT INSUFFICIENT TO CLASSIFY (e.g. IARC GROUP 3)

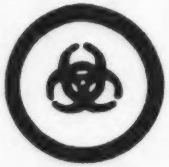
CLASSIFICATION: REPRODUCTIVE TOXICITY

CPR SECTION 55	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2	- HAZARD SYMBOL. NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	- SUBDIVISION A, VERY TOXIC A) EVIDENCE OF STERILITY OR ADVERSE EFFECT ON REPRODUCTIVE CAPABILITY FOLLOWING WORKPLACE EXPOSURE. OR B) IF SAME EVIDENCE IS SHOWN ONE OR TWO GENERATION REPRODUCTIVE TOXICITY ANIMAL ASSAYS	- NO SPECIFIC CRITERIA - WOULD BE INCLUDED IN REPRODUCTIVE TOXIN, TARGET ORGAN CATEGORIZATION	- NO SPECIFIC CRITERIA - CONSIDER CHRONIC TOXIC EFFECT CRITERIA

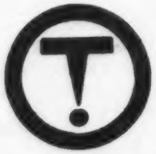
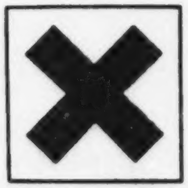
CLASSIFICATION: SKIN SENSITIZATION

CPR SECTION 61	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	Xi 
CRITERIA	- SUBDIVISION B, TOXIC A) OECD 406 - PRODUCES RESPONSE IN ≥ 30% OF TEST ANIMALS WITH USE OF AN ADJUVANT - PRODUCES RESPONSE IN ≥ 15% OF TEST ANIMALS WITHOUT USE OF AN ADJUVANT B) POSITIVE EVIDENCE OF WORKPLACE SKIN SENSITIZATION	- SKIN AND LUNG SENSITIZERS COVERED UNDER SENSITIZER CLASS -- SEE RESPIRATORY SENSITIZATION	- IRRITANT (R43) - IF SENSITIZATION REACTION IS NOTED IN A SIGNIFICANT HUMAN OR ANIMAL POPULATION FOLLOWING EXPOSURE - SAME OECD 406 TEST RESULTS CONSIDERED

CLASSIFICATION: BIOHAZARDOUS INFECTIOUS MATERIAL

CPR SECTION 64	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 3		
CRITERIA	- AN ORGANISM AND ITS TOXINS THAT HAS BEEN SHOWN OR IS BELIEVED TO CAUSE DISEASE IN PERSONS OR ANIMALS	- NOT CLASSIFIED	- NOT CLASSIFIED

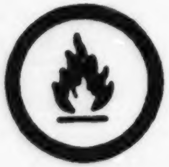
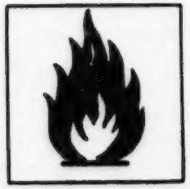
CLASSIFICATION: CHRONIC TOXIC EFFECTS

CPR SECTION 59	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	Xn 
CRITERIA	- SUBDIVISION B, TOXIC - EFFECTS OF SUFFICIENT SEVERITY TO THREATEN LIFE OR CAUSE SERIOUS PERMANENT IMPAIRMENT IN ≥ 90 DAY TESTS AT: A) 10 MG/KG/DAY < ORAL DOSE ≤ 100 MG/KG/DAY B) 20 MG/KG/DAY < DERMAL DOSE ≤ 200 MG/KG/DAY C) GASES AND VAPOURS: 25 PPM < INHALATION CONC. ≤ 250 PPM DUST, MIST, FUME: 10 MG/M^3 < INHALATION CONC. ≤ 100 MG/M^3	- NO CRITERIA SPECIFIED - TARGET ORGAN EFFECTS CONSIDERED	- HARMFUL - (R48) DANGER OF FUNCTIONAL DISTURBANCE OR MORPHOLOGICAL CHANGE BY REPEATED OR PROLONGED EXPOSURE AT: A) ORAL DOSE ≤ 50 MG/KG/DAY B) DERMAL DOSE ≤ 100 MG/KG/DAY C) INHALATION CONC. ≤ 500 MG/M^3 - APPLY DIRECTLY TO 90 DAY SUB-CHRONIC GUIDELINES TO INTERPRET SUB-ACUTE (28 DAY) OR CHRONIC (2 YEARS) STUDIES

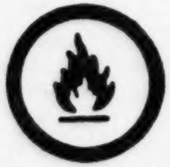
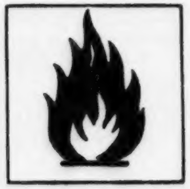
CLASSIFICATION: COMPRESSED GAS

CPR SECTION 34	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS A	- NO HAZARD SYMBOL RECOMMENDED IN ANSI STANDARD ON PRECAUTIONARY LABELLING	- NOT CLASSIFIED
CRITERIA	A) CRITICAL TEMPERATURE $<50^{\circ}$C B) ABSOLUTE VAPOUR PRESSURE $>$ 294 kPa at 50°C C) ABSOLUTE PRESSURE IN PRESSURE VESSEL $>$ 275 kPa at 21.1°C OR $>$ 717 kPa at 54.4°C D) IN LIQUID STATE ABSOLUTE VAPOUR PRESSURE $>$275 kPa at 37.8°C (ASTM P. 323-82, 1981)	- NOT SPECIFIED - NOT SPECIFIED - SAME AS WHMIS CRITERIA $>$40 psi at 70°F $>$104 psi at 130°F $>$40 psi at 100°F	- NOT CLASSIFIED

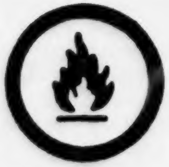
CLASSIFICATION: FLAMMABLE GAS

CPR SECTION 36	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS B, DIVISION 1	- FLAME SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	F 
CRITERIA	- COMPRESSED GAS WHICH FORMS FLAMMABLE MIXTURE WITH AIR AT ATMOSPHERIC PRESSURE A) AT <13% VOLUME OR B) OVER A 12% CONCENTRATION RANGE	- SAME AS WHMIS CRITERIA	- HIGHLY FLAMMABLE A GAS WHICH IS FLAMMABLE IN AIR AT NORMAL PRESSURE WOULD BE LABELLED EXTREMELY FLAMMABLE (R12) UNDER THE HIGHLY FLAMMABLE CLASS - INCLUDES EXTREMELY FLAMMABLE LIQUEFIED GASES (R13)

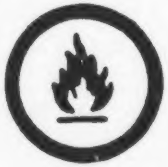
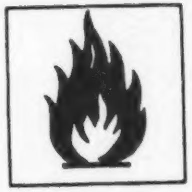
CLASSIFICATION: FLAMMABLE SOLID

CPR SECTION 39	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS B, DIVISION 4	- FLAME SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	A) CAUSES FIRE THROUGH FRICTION OR RETAINED HEAT FROM PROCESSING B) WILL READILY IGNITE AND BURNS VIGOROUSLY C) IGNITES READILY AND BURNS AT A RATE >0.254 CM/SECOND (0.1 INCH/SECOND) ALONG ITS MAJOR AXIS D) IS INCLUDED IN DIVISION I OF CLASS 4 OF PART III, TDG	- SAME AS WHMIS CRITERIA, PLUS - WILL CAUSE FIRE FROM: ABSORPTION OF MOISTURE OR SPONTANEOUS CHEMICAL CHANGE	- HIGHLY FLAMMABLE WILL READILY IGNITE AND CONTINUE TO BURN (R11)

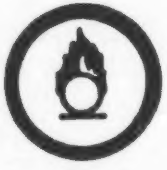
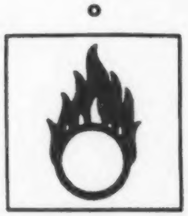
CLASSIFICATION: FLAMMABLE AEROSOLS

CPR SECTION 40	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS B, DIVISION 5	- FLAME SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	- PACKAGED IN AEROSOL CONTAINER - WHEN TESTED (SCHEDULE VI) YIELDS A FLAME PROJECTION AT FULL VALVE OPENING OR A FLASHBACK AT ANY DEGREE OF VALVE OPENING	- SAME AS WHMIS CRITERIA - SAME AS WHMIS CRITERIA	- CLASSIFIED UNDER DIFFERENT REGULATIO FLAMMABLE IF: - CONTAIN FLAMMABLE GAS - LIQUIDS WITH FLASHPOINT LESS THAN 100°C - CONTAINER CONTENT ≥45 WT % OR ≥250 g OF FLAMMABLE COMPONENTS

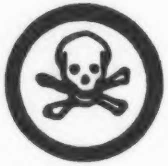
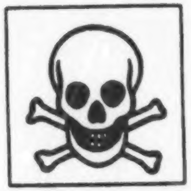
CLASSIFICATION: REACTIVE FLAMMABLE MATERIALS

CPR SECTION 41	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS B, DIVISION 6		F 
CRITERIA	A) SPONTANEOUSLY COMBUSTIBLE UNDER NORMAL CONDITIONS OR LIABLE TO HEAT IN CONTACT WITH AIR TO THE POINT OF BURNING B) EMITS A FLAMMABLE GAS OR BECOMES SPONTANEOUSLY COMBUSTIBLE ON CONTACT WITH WATER OR WATER VAPOUR	- INCLUDED UNDER FLAMMABLE SOLIDS	- HIGHLY FLAMMABLE SPONTANEOUSLY FLAMMABLE IN AIR (R17) CONTACT WITH WATER LIBERATES HIGHLY FLAMMABLE GASES (R15)

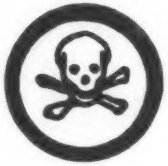
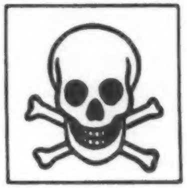
CLASSIFICATION: OXIDIZING MATERIAL

CPR SECTION 42	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS C	- HAZARD SYMBOL NOT RECOMMENDED IN ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	A) CAUSES OR CONTRIBUTES TO THE COMBUSTION OF ANOTHER MATERIAL BY YIELDING OXYGEN OR ANY OTHER OXIDIZING MATERIAL B) IS AN ORGANIC PEROXIDE CONTAINING O-O STRUCTURE	- SAME AS WHMIS CRITERIA - ORGANIC PEROXIDES CLASSED SEPARATELY	(R11) ORGANIC PEROXIDES HAVING FLAMMABLE PROPERTIES IN THEMSELVES (R8) CONTACT WITH COMBUSTIBLE MATERIAL MAY CAUSE FIRE (R9) EXPLOSIVE WHEN MIXED WITH COMBUSTIBLE MATERIAL

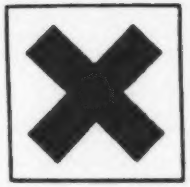
CLASSIFICATION: ACUTE LETHALITY

CPR SECTION 49	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 1	- SKULL AND CROSSBONES SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T 
CRITERIA	- SUBDIVISION B, TOXIC A) $50\ MG/KG < ORAL\ LD50 \leq 500\ MG/KG$ B) $200\ MG/KG < DERMAL\ LD50 \leq 1000\ MG/KG$ C) INHALATION - VAPOUR (4 HR) $1500\ PPM < LC50 \leq 2500\ PPM$ D) INHALATION - DUST, MIST, FUME (4 HR) $500\ MG/M^3 < LC50 \leq 2500\ MG/M^3$	- TOXIC A) ORAL - SAME AS WHMIS B) DERMAL - SAME AS WHMIS C) INHALATION - VAPOUR or GAS (1 HR) $200\ PPM < LC50 \leq 2000\ PPM$ INHALATION - DUST, FUME, MIST (1 HR) $2000\ MG/M^3 < LC50 \leq 20,000\ MG/M^3$	- TOXIC - $25\ MG/KG < ORAL\ LD50 \leq 200\ MG/KG$ (R25) - $50\ MG/KG < DERMAL\ LD50 \leq 400\ MG/KG$ (R24) - INHALATION (R23) (4 HR) $500\ MG/M^3 < LC50 \leq 2000\ MG/M^3$ - SERIOUS NON-LETHAL ACUTE EFFECTS AT SIMILAR DOSES (R39)

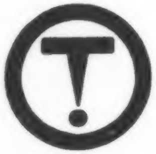
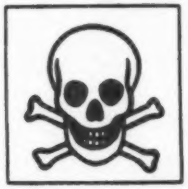
CLASSIFICATION: ACUTE LETHALITY

CPR SECTION 46	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 1	- SKULL AND CROSSBONES SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T+ 
CRITERIA	- SUBDIVISION A, VERY TOXIC A) ORAL LD50 ≤ 50 MG/KG B) DERMAL LD50 ≤ 200 MG/KG C) GASES LC50 ≤ 2500 PPM (4 HR) D) VAPOURS LC50 ≤ 1500 PPM (4 HR) E) DUST, MIST, FUME, LC50 ≤ 500 MG/M^3	- HIGHLY TOXIC A) ORAL - SAME AS WHMIS B) DERMAL - SAME AS WHMIS C) INHALATION GAS AND VAPOUR (1 HR) LC50 ≤ 200 PPM DUST, MIST, FUME (1 HR) LC50 ≤ 2000 MG/M^3	- VERY TOXIC - ORAL LD50 ≤ 25 MG/KG (R28) - DERMAL LD50 ≤ 50 MG/KG (R27) - INHALATION LC50 ≤ 500 MG/M^3 (R26) (4 HR) - SERIOUS NON-LETHAL ACUTE EFFECTS AT SIMILAR DOSES (R39)

CLASSIFICATION: ACUTE LETHALITY

CPR SECTION	WHMIS	OSHA	EEC
HAZARD SYMBOL			Xn 
CRITERIA	- SOME OVERLAP WITH ORAL AND DERMAL ACUTE LETHALITY, TOXIC CRITERIA	- SOME OVERLAP WITH ORAL AND DERMAL ACUTE LETHALITY, TOXIC CRITERIA	- HARMFUL - 200 MG/KG $<$ ORAL LD50 $\leq$ 2000 MG/KG (R22) - 400 MG/KG $<$ DERMAL LD50 $\leq$ 2000 MG/KG - INHALATION (R20) (4 HR) 2000 $MG/M^3 <$ LC50 $\leq$ 20,000 MG/M^3 - SERIOUS NON-LETHAL ACUTE EFFECTS AT SIMILAR DOSES (R40)

CLASSIFICATION: CHRONIC TOXIC EFFECTS

CPR SECTION 52	WHMIS	OSHA	EEC
HAZARD SYMBOL	 CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T 
CRITERIA	- SUBDIVISION A, VERY TOXIC - EFFECTS WITH SUFFICIENT SEVERITY TO THREATEN LIFE OR CAUSE SERIOUS PERMANENT IMPAIRMENT IN ≥ 90 DAY TESTS AT: A) ORAL DOSE ≤ 10 MG/KG/DAY B) DERMAL DOSE ≤ 20 MG/KG/DAY C) INHALATION CONCENTRATION ≤ 25 PPM GAS OR VAPOUR ≤ 10 MG/M^3 DUST, MIST, FUME	- NO CRITERIA SPECIFIED - MUST CONSIDER SPECIFIC TARGET ORGAN EFFECTS FROM ALL SOURCES OF INFORMATION	- TOXIC - CLEAR FUNCTIONAL DISTURBANCE OR MORPHOLOGICAL CHANGE WHICH HAVE TOXICOLOGICAL SIGNIFICANCE LIKELY TO BE CAUSED BY REPEATED OR PROLONGED EXPOSURE AT DOSES SIGNIFICANTLY LOWER THAN HARMFUL CLASS DOSES (R48)